**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF VIRGINIA**
**NORFOLK DIVISION**

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| GIANT EAGLE, INC.,<br><br>Plaintiff,<br><br>v.<br><br>MERCK & CO., INC.; MERCK SHARP & DOHME CORP.; SCHERING-PLOUGH CORP.; SCHERING CORP.; MSP SINGAPORE CO. LLC; GLENMARK PHARMACEUTICALS LTD.; and GLENMARK PHARMACEUTICALS INC., USA,<br><br>Defendants. | Civil Action No. _____ |

**COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff Giant Eagle, Inc. ("Giant Eagle") brings this civil antitrust action against Defendants Merck & Company, Inc., Merck Sharp & Dohme Corporation, Schering-Plough Corporation, Schering Corporation, and MSP Singapore Company LLC (collectively "Merck"), and Glenmark Pharmaceuticals Limited and Glenmark Pharmaceuticals Inc., USA (collectively "Glenmark"), and for its Complaint alleges as follows:

## I. INTRODUCTION

1. This is a civil antitrust action seeking permanent injunctive relief, treble damages, and other relief to redress an unlawful reverse-payment settlement agreement between Merck and Glenmark/Par pursuant to which Merck agreed to pay Glenmark approximately $800 million to delay its launch of generic Zetia for nearly five years. Merck's payment to Glenmark took the form of an agreement not to launch an authorized generic version of Zetia in competition with Glenmark's generic. Such agreements, in addition to being unlawful reverse-payment agreements under *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), are *per se* unlawful horizontal market-allocation agreements in which the relevant market is allocated temporally rather than geographically—*i.e.*, Glenmark agreed not to compete with Merck for nearly five years and, in return, Merck agreed not to compete with Glenmark for an additional six months. Par, named herein as a co-conspirator, became a member of the conspiracy by approving the unlawful settlement agreement and agreeing to become the exclusive distributor of Glenmark's generic Zetia.

2. Reverse-payment agreements that include no-authorized-generic ("no-AG") provisions are even more anticompetitive than reverse-payment agreements in which the payment is in cash. While cash payments delay generic entry, no-AG provisions delay generic entry *and* continue to restrict competition even after generic entry because they ensure that only one generic will be available rather than two, which means that purchasers of the generic drug

will pay higher prices. Stated differently, the compensation received by the generic manufacturer in a no-AG agreement comes in part from the brand manufacturer, which gives up the profits it would have earned by selling an authorized generic, but also in part from purchasers of the generic, who pay higher prices. Because competition from an authorized generic drives down generic prices, the cost to the brand company of forgoing such sales is less than the benefit to the generic, with purchasers paying the difference. This asymmetry explains the popularity of no-AG agreements.

3. In the absence of the unlawful agreement between Merck and Glenmark/Par, both companies would have launched generic versions of Zetia as early as December 2011 and, in any event, long before the actual entry date of December 12, 2016. Additional generics would have entered the market six months later. Giant Eagle and other purchasers would have substituted lower-priced generic Zetia for higher-priced branded Zetia for the vast majority of their purchases of the drug.

4. Giant Eagle is a direct purchaser or assignee of direct purchasers of Zetia and members of the putative class for which class certification has been sought in *FWK Holdings, LLC v. Merck & Co., Inc.*, Civil Action No. 2:18-cv-23, pending in this Court. The statute of limitations applicable to Giant Eagle's claims has been tolled at least since the filing of the *FWK Holdings* case on January 16, 2018.

## II. PARTIES

5. Giant Eagle is a Pennsylvania corporation having its principal place of business at 101 Kappa Drive, Pittsburgh, PA 15238. Giant Eagle owns and operates retail stores in several states at which it dispenses prescription drugs, including Zetia, to the public. Giant Eagle brings this action on its own behalf and as the assignee of McKesson Corporation, a national pharmaceutical wholesaler, which during the relevant period purchased Zetia directly from

Merck for resale to Giant Eagle and which has assigned its claims arising out of those purchases to Giant Eagle.

6. Defendant Merck & Co., Inc. is a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is the parent corporation of Defendants Merck Sharp & Dohme Corporation and MSP Singapore Company LLC.

7. Defendant Merck Sharp & Dohme Corporation is a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It is a subsidiary of Defendant Merck & Co., Inc.

8. Defendant Schering-Plough Corporation was a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

9. Defendant Schering Corporation was a New Jersey corporation having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. It was a wholly owned subsidiary of Schering-Plough Corporation.

10. Merck & Co., Inc. acquired Schering-Plough Corporation in 2009. As part of that transaction, Merck & Co., Inc. merged into Schering-Plough Corporation, which subsequently changed its name to Merck & Co., Inc. The company formerly known as Merck & Co., Inc. changed its name to Merck Sharp & Dohme Corporation.

11. Defendant MSP Singapore Company LLC ("MSP") is a Delaware limited liability company having its principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033. MSP is a subsidiary of Merck & Co., Inc.

12. Defendant Glenmark Pharmaceuticals Limited is an Indian corporation having its principal place of business at Glenmark House, B.D. Sawant Marg, Andheri (E), Mumbai 400

099, India, and its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai 400 026, India.

13. Defendant Glenmark Pharmaceuticals Inc., USA is a Delaware corporation having its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. It is a wholly owned subsidiary of Glenmark Pharmaceuticals Limited. From 2002, when it was first incorporated, Glenmark Pharmaceuticals Inc., USA has been referred to as, done business as, and/or formally been known as, both Glenmark Pharmaceuticals Inc., USA and, at times, Glenmark Generics Inc., USA. Glenmark Pharmaceuticals Limited, and Glenmark Pharmaceuticals Inc., USA (including Glenmark Generics Inc., USA) are collectively referred to in this complaint as "Glenmark."

14. Co-Conspirator Par Pharmaceutical, Inc. ("Par") is a New York corporation having its principal place of business in Chestnut Ridge, New York. Par is a subsidiary of Endo International plc, an Irish corporation with its U.S headquarters located in Malvern, Pennsylvania. In September 2015, Endo completed its acquisition of Par Pharmaceuticals Holdings, Inc. and its subsidiaries, including Par, and combined it with Endo's existing generics subsidiary, Qualitest Pharmaceuticals. In this complaint, "Par" encompasses its relevant predecessors and successors.

15. All of the actions attributed to Defendants and Co-Conspirator Par in this Complaint were authorized, ordered and done by their respective officers, agents, employees or other representatives while actively engaged in the management of that Defendant's or Co-Conspirator's affairs and within the course and scope of their agency or employment, and/or with actual, apparent or ostensible authority.

## III. JURISDICTION AND VENUE

16. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), seeking treble damages, costs of suit and reasonable attorney's fees for the injury sustained by Giant Eagle as a result of Merck's unlawful foreclosure of generic prescription ezetimibe sales in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

17. This Court has personal jurisdiction over Defendants, and venue is proper in this district pursuant to 15 U.S.C. §§ 15(a) and 22 and 28 U.S.C. § 1391. During the relevant period, each Defendant resided, transacted business, was found, or had agents in this district, and a substantial portion of the alleged unlawful activity was carried out in this district.

## IV. BACKGROUND

### A. Characteristics of the Prescription Pharmaceutical Marketplace

18. The marketplace for the sale of prescription pharmaceutical products in the United States suffers from a significant imperfection that brand manufacturers can exploit in order to obtain or maintain market power in the sale of a particular pharmaceutical composition. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the payment obligation and the choice of products, the price of the product plays an appropriate role in the person's choice of products and, consequently, the manufacturers have an appropriate incentive to lower the prices of their products.

19. The pharmaceutical marketplace, however, is characterized by a "disconnect" between the payment obligation and the product selection. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Zetia, to patients without a prescription written by a doctor. The prohibition on dispensing certain products without a prescription

introduces a disconnect between the payment obligation and the product selection. The patient (and in most cases his or her insurer) has the obligation to pay for the pharmaceutical product, but the patient's doctor chooses which product the patient will buy.

20. Brand manufacturers exploit this price disconnect by employing large forces of sales representatives to visit doctors' offices and persuade them to prescribe the manufacturer's products. These sales representatives do not advise doctors of the cost of the branded products. Moreover, studies show that doctors typically are not aware of the relative costs of brand pharmaceuticals and, even when they are aware of the relative costs, they are insensitive to price differences because they do not have to pay for the products. The result is a marketplace in which price plays a comparatively unimportant role in product selection.

21. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity in turn gives brand manufacturers the ability to raise price substantially above marginal cost without losing so many sales as to make the price increase unprofitable. The ability to profitably raise price substantially above marginal cost is what economists and antitrust courts refer to as market power. The result of the market imperfections and marketing practices described above is to allow brand manufacturers to gain and maintain market power with respect to many branded prescription pharmaceuticals.

### B. The Regulatory Structure for Approval of Generic Drugs and the Substitution of Generic Drugs for Brand Name Drugs

22. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

23. When the FDA approves a brand manufacturer's NDA, the drug product is listed in an FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." The manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may subsequently list in the Orange Book within thirty days of issuance any such patents issued after the FDA approves the NDA. 21 U.S.C. §§ 355(b)(1) & (c)(2).

24. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

**C. The Hatch-Waxman Amendments**

25. The Hatch-Waxman Amendments (also simply "Hatch-Waxman"), enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly New Drug Applications ("NDAs"). See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, as amended (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and is absorbed at the same rate and to the same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The

FDA assigns oral-dosage-form generic drugs that are therapeutically equivalent to their brand-name counterpart an "AB" rating.

26. Bioequivalence exists when the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the branded counterpart. 21 U.S.C. § 355(j)(8)(B).

27. Congress enacted the Hatch-Waxman Amendments to expedite the entry of legitimate (non-infringing) generic competitors, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

28. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historically high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for branded and generic drugs totaled $21.6 billion; by 2009 total prescription drug revenue had increased many-fold to $300 billion.

**D. Paragraph IV Certifications**

29. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA (a "Paragraph I certification");
ii. that the patent for the brand drug has expired (a "Paragraph II certification");
iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "Paragraph III certification"); or
iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

30. If a generic manufacturer files a Paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of: (a) the passage of 30 months, or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

31. As an incentive to spur manufacturers to seek approval of generic alternatives to branded drugs, the first generic manufacturer to file an ANDA containing a Paragraph IV certification typically gets a period of protection from competition from other generic versions of the drug. For Paragraph IV certifications made after December 2003, the first generic applicant receives 180 days of market exclusivity. This means that the first approved generic is the only available generic for at least six months, which effectively creates a duopoly between the brand company and the first-filing generic during this period. This 180-day exclusivity period is extremely valuable to generic companies. While only one generic is on the market, the generic price, while lower than the branded price, is much higher than after multiple generic competitors enter the market. Generics are usually at least 25% less expensive than their brand name counterparts when there is a single generic competitor, but this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market. Being able to sell at the higher duopoly price for six months may be worth hundreds of millions of dollars.

32. The first generic applicant can help the brand manufacturer "game the system" by delaying not only its own market entry, but also the market entry of all other generic manufacturers. The first generic applicant, by agreeing not to begin marketing its generic drug, thereby delays the start of the 180-day period of generic market exclusivity. This tactic creates a "bottleneck" because later generic applicants cannot launch until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

**E. Benefits of Generic Drugs**

33. Generic versions of brand name drugs contain the same active ingredient and are determined by the FDA to be just as safe and effective, as their brand name counterparts. The only material difference between generic and brand name drugs is their price. The launch of a generic drug thus usually brings huge cost savings for all drug purchasers. The Federal Trade Commission ("FTC") estimates that, by one year after market entry, the generic version takes over 90% of the brand's unit sales and sells for 15% of the price of the brand name product. In retail pharmacy chains, such as Giant Eagle, a generic typically achieves at least an 80% substitution rate within 90 days. As a result, brand name companies, such as Merck, view competition from generic drugs as a grave threat to their bottom lines.

34. Due to the price differentials between brand and generic drugs, and other institutional features of the pharmaceutical industry, including state generic substitution laws, pharmacists liberally and substantially substitute for the generic version when presented with a prescription for the brand-name counterpart. Since passage of the Hatch-Waxman Amendments, every state has adopted substitution laws that either require or permit pharmacies to substitute generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise by writing "dispense as written" or similar language on the prescription).

35. There is an incentive to choose the less expensive generic equivalent in every link in the prescription drug chain. Pharmaceutical wholesalers and retailers pay lower prices to acquire generic drugs than to acquire the corresponding brand-name drug. Health insurers and patients also benefit from the lower prices of generic products.

36. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to substitute for, and to compete with, the branded drug, and therefore the brand manufacturer can continue to profitably charge very high prices (relative to cost) without losing sales. As a result, brand manufacturers, who are well aware of generics' rapid erosion of their brand sales, have a strong incentive to delay the introduction of generic competition into the market, including by using tactics such as the agreement at issue here.

**F. The Impact of Authorized Generics**

37. The 180-day marketing exclusivity to which first-filer generics may be entitled does not prevent a brand manufacturer from marketing its own generic alternative to the brand drug during the exclusivity period pursuant to its own approved NDA. Such an "authorized generic" is literally identical to the brand drug but is sold as a generic product either by the brand manufacturer itself or through an authorized third party. Competition from an authorized generic during the 180-day exclusivity period substantially reduces the price of both the ANDA filer's generic drug and the authorized generic and, in addition, forces the first-filer to share the generic sales made at those lower prices with the brand-name manufacturer. Both of these effects reduce the first-filer's revenues and profits.

38. In its study, *Authorized Generic Drugs: Short-term Effects and Long-Term Impact* (August 2011), the Federal Trade Commission found that authorized generics capture a significant portion of sales, reducing the revenues generated by the first-filer's generic product by approximately 50% during the 180-day exclusivity period. The first-filing generic makes

significantly less money when it faces competition from an authorized generic because (1) the authorized generic takes a large share of unit sales away from the first-filer; and (2) the presence of an additional generic in the market causes prices to decrease.

39. Although first-filing generic manufacturers make significantly less money when they must compete with an authorized generic during the first 180 days, drug purchasers benefit from the lower prices caused by competition between the authorized generic and the first-filing generic.

40. As a practical matter, authorized generics are the only means by which brand-name manufacturers engage in price competition with manufacturers of AB-rated generic drugs. Brand-name manufacturers generally do not reduce the price of their branded drug in response to the entry of an AB-rated generic. Instead, they either raise the price to extract higher prices from the small number of "brand-loyal" patients or, more typically, they continue to raise the price of the branded drug at the same rate at which it was raised prior to generic entry.

41. Given the significant negative impact of an authorized generic on the first-filing generic's revenues, and the absence of any other form of price competition from the branded manufacturer, a brand manufacturer's agreement not to launch an authorized generic has tremendous economic value to the generic manufacturer. Brand manufacturers have used such agreements as a way to pay the first-filer to delay entering the market. Such agreements deprive drug purchasers such as Giant Eagle of the lower prices resulting from two forms of competition. During the initial period of delay agreed to by the ANDA filer, they effectively eliminate all competition from AB-rated generic products and allow the brand manufacturer to preserve its monopoly. And, during the period in which the branded company has agreed not to sell an authorized generic, they eliminate competition between the ANDA filer's generic and the authorized generic, giving the ANDA filer a monopoly on generic sales.

42. As a means of compensating first-filing generic manufacturers, brand manufacturers prefer no-AG agreements to cash payments because, in the case of no-AG agreements, a portion of the compensation is paid by purchasers of the drug in the form of higher generic drug prices. The generic manufacturer receives not only the profits that the brand manufacturer would have made by launching an authorized generic in competition with the ANDA filer's product, but also the higher prices that result from the absence of that competition. Thus, the payment to the generic manufacturer is shared between the brand manufacturer and the generic manufacturer's customers.

## V. OPERATIVE FACTS

### A. Cholesterol-lowering drugs.

43. Cholesterol is essential in constructing and maintaining membranes in animal cells. It makes up part of the myelin sheath that insulates nerve cells and facilitates conducting nerve impulses. It is also an important precursor for making vitamin D and steroid hormones in the body.

44. Our bodies derive cholesterol from two sources. We make cholesterol, mostly in our livers. Our bodies also absorb cholesterol through our intestines. This absorption includes both cholesterol from the foods we eat and the cholesterol we make. About 50% of the cholesterol made in our livers is reabsorbed through our intestines.

45. High cholesterol is associated with coronary heart disease and atherosclerosis in some populations. Atherosclerotic coronary heart disease is a major cause of death and cardiovascular morbidity in the western world.

46. In the 1950s, scientists developed several drugs thought to lower cholesterol levels.

47. In 1953, scientists in France reported that phylacetic acid and its analogues – fibrates – lowered cholesterol levels. This discovery led to the approval of ethyl ester clofibrate in the U.S. in 1967; it was later found to have unacceptable side effects and was replaced with other fibrates.[1]

48. In the 1970s and 80s, scientists discovered a group of cholesterol-lowering drugs known as statins. Statins lower cholesterol levels by inhibiting the enzyme that regulates the production of cholesterol in the liver, HMG-CoA reductase. In 1987, Merck launched the first statin: lovastatin. Merck later launched a second statin: simvastatin. Other drug companies – including Sankyo, Novartis, Pfizer, and AstraZeneca – followed suit. Statins, as a class, were for many years the most profitable drugs in pharmaceutical history.

49. The 1990s saw a renewed interest in fibrates as (1) cholesterol lowering drugs had become big business, (2) their mechanism of action became better understood, and (3) clinical trials demonstrated the efficacy of fibrates on cardiovascular events. Scientists had discovered that fibrates inhibited the enzyme Acyl-CoA cholesterol acyltransferase (ACAT), which blocked the absorption of cholesterol in the intestine (and may also inhibit cholesterol deposited within vascular walls). And clinical data showed that fibrates worked. So, while statins had become first line treatments, fibrates were still widely prescribed.

### B. Early 1990s: Merck develops hydroxyl-substituted azetidinone compounds useful as hypocholesterolemic agents.

50. In the early 1990s, Merck embarked on a broad chemical program to discover novel ACAT inhibitors. Scientists working in Schering's New Jersey facilities began developing

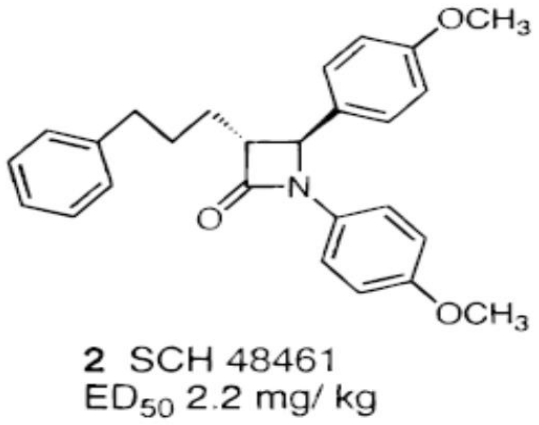
[1] In the 1980s, scientists discovered that fibrates worked by interacting with the peroxiosome proliferator-activated receptors (PPAR-α) in the liver, muscle, and other tissues.

azetidinone compounds to reduce cholesterol levels in humans. Those scientists included Stuart B. Rosenblum, Sundeep Dugar, Duane A. Burnett, John W. Clader, and Brian McKittrick.

51. In lab experiments conducted over a couple of years or less, these scientists identified a lead compound, SCH48461, and inherent metabolites and metabolite-like analogues of that compound, including SCH58235 or "ezetimibe." (Ezetimibe would eventually become the active ingredient in Zetia).

52. SCH 48461 is (3R,3S)-1,4-bis-(4-methoxyphenyl)-3-(3-phenylpropyl)-2-azetidinone.[2] It is pictured in Figure 4 below.

**Figure 4. SCH 48461**



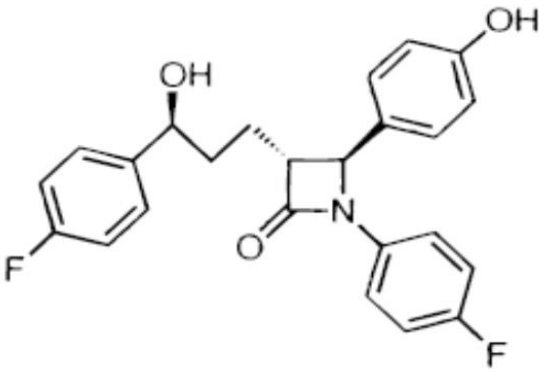

53. SCH 58235 is 1-(4-fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3s)-hydroxypropyl]-(4S)-(4-hydroxypheyl)-2-azetidinone.[3] The use of halogen to block sites of metabolism was then well known. To create SCH 58235, Merck scientists used routine laboratory techniques to add

[2] *See* Brian G. Salisbury, *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption*, SCH 48461, 115 Atherosclerosis 45 (1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

[3] Stuart B. Rosenblum, *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998).

fluorine to the two phenyl rings, in order to lessen the likelihood of hydroxylation (and thereby keep the compound in the body longer). It is pictured in Figure 5 below.

**Figure 5. SCH 58235, Ezetimibe**




**1** SCH 58235
$ED_{50}$ 0.04 mg/ kg

54. Upon discovering these and other useful compounds (and their metabolites) and recognizing their potential to be developed into lucrative prescription drugs down the road, Merck set out to obtain broad patent protection.

55. Merck knew that publishing journal articles about its research and development could potentially undermine its ability to patent its inventions. So, while its discoveries occurred in the early 1990s, its scientists did not publish their discoveries until after the first patent application was filed and, in some instances, only wrote about the development process over a decade later.[4]

[4] *See* John W. Clader, *Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors*, 5 Current Topics Med. Chem. 243 (2005); John W. Clader, *The Discovery of Ezetimibe: A View from Outside the Receptor*, 47 J. Med. Chem. 1 (2004); Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998); Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997); Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996); John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-*

**C. 1993-1998: Merck applies for, and obtains, the original azetidinone patents (the '365, '115, and '966 patents).**

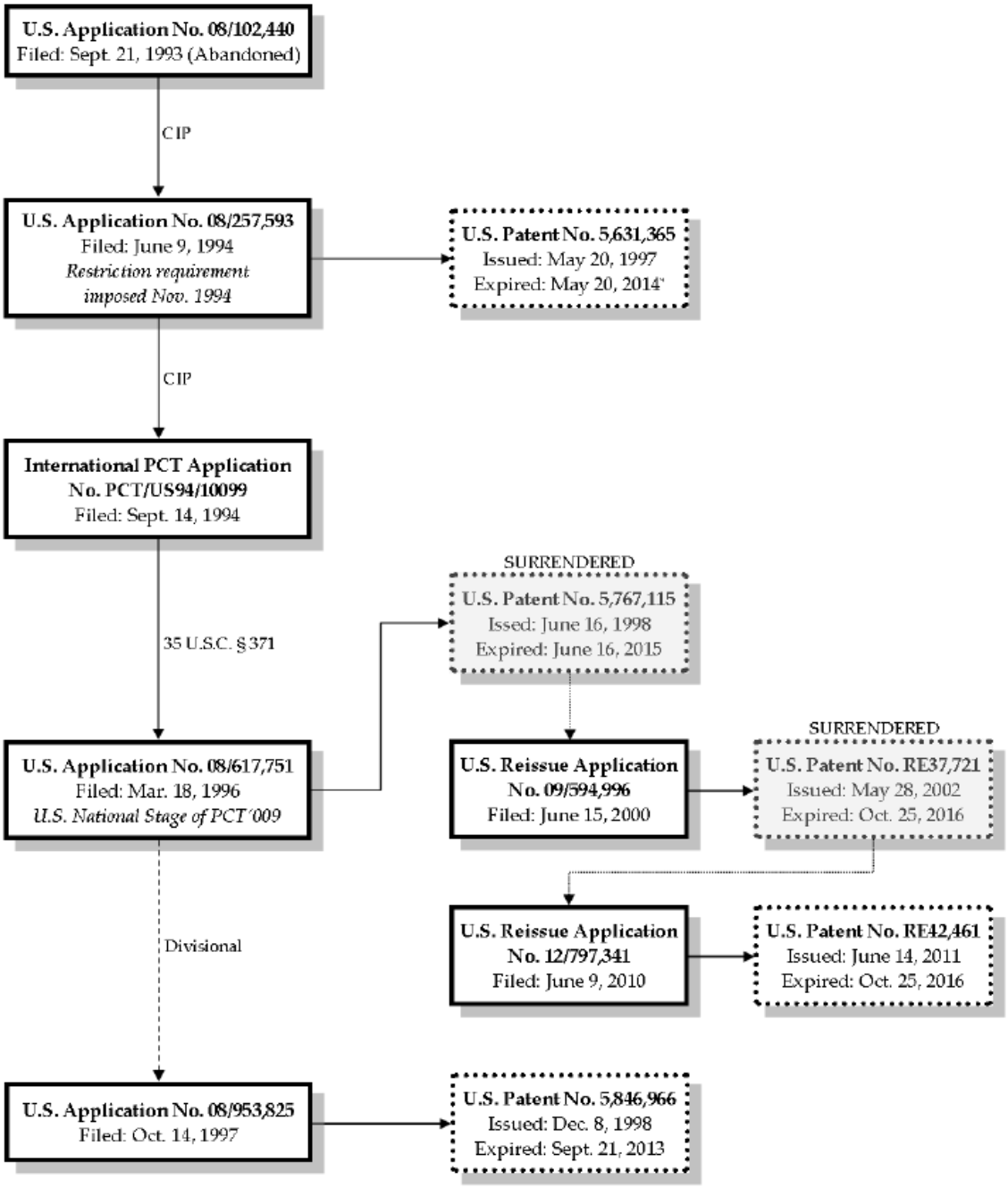
56. Beginning in 1993, Merck filed a series of related U.S. patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.[5] Three issued as patents; one of these then reissued twice.

57. For shorthand, the family of patents resulting from these applications can be referred to as "the azetidinone patents." All told, the azetidinone patents include the '365 patent, the '115 patent, the '966 patent, the RE'721 patent, and the RE'461 patent.

*Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996); Brian A. McKittrick et al., *Stereoselective Synthesis and Biological Activity of Cis Azetidinones as Cholesterol Absorption Inhibitors*, 16 Bioorganic & Med. Chem. Letters 1947 (1996); Brian G. Salisbury et al., *Hypocholesterolemic Activity of a Novel Inhibitor of Cholesterol Absorption, SCH 48461*, 115 Atherosclerosis 45 (1995); Sundeep Dugar et al., *Gamma-Lactams and Related Compounds as Cholesterol Absorption Inhibitors: Homologs of the β-Lactam Cholesterol Absorption Inhibitor SCH 48461*, 24 Bioorganic & Med. Chem. Letters 2947 (1995); Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995); Duane A. Burnett et al., *2-Azetidinones as Inhibitors of Cholesterol Absorption*, 37 J. Med. Chem. 1733 (1994).

[5] All of the patent applications and communications with the PTO described herein were done by Schering Corporation and its agents, unless otherwise noted.

**Figure 6. The Azetidinone Patents**




*All expiration dates are calculated without pediatric exclusivity extensions.

**(1) 1993-1994: Merck files two patent applications addressing hydroxyl-substituted azetidinone compounds useful as hypocholesteremic agents.**

58. On September 21, 1993, Merck filed U.S. Patent Application 102,440, entitled "Hydroxy-Substituted Azetidinone Compounds Useful As Hypocholesterolemic Agents." Merck abandoned the application.

59. On June 9, 1994, Merck filed U.S. Patent Application 257,593 as a continuation-in-part of the abandoned '440 application.

60. Both the '440 application and the '593 application disclosed that the inventions described were useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis – the hardening and narrowing of the arteries due to build-up of fats and cholesterol on artery walls. These applications explained that the liver is the major organ responsible for cholesterol biosynthesis and is the prime determinant of plasma cholesterol levels. When intestinal cholesterol absorption is reduced, less cholesterol is delivered to the liver, which makes less hepatic lipoprotein and clears more plasma cholesterol (mostly LDL). As Merck put it, "the net effect of inhibiting intestinal cholesterol absorption is a decrease in plasma cholesterol levels."

61. Merck went on to prosecute the '593 application for about three years.

**(2) 1994-1996: Merck files a third and fourth patent application addressing hydroxyl-substituted azetidinone compounds.**

62. On September 14, 1994, Merck filed the PCT/US94/10099 application as a continuation-in-part of the '593 application. The PCT'099 application added two example compounds in the specification, 3L and 3M, as well as *in vivo* data for 3L, 3M, and 6A-1.

63. On March 18, 1996, the PCT'0099 application became U.S. Patent Application No. 617,751. The specification for the '751 application, as filed, was identical to the specification of the PCT'0099 application.

64. Merck went on to prosecute the '751 application for a little over two years.

**(3) 1994-Early 1997: Merck obtains its first azetidinone patent, covering processes (the '365 patent).**

65. On May 20, 1997, the '593 application – Merck's second azetidinone patent application – issued as U.S. Patent No. 5,631,365. The '365 patent was the first-issued Merck azetidinone patent.

66. The named inventors of the '365 patent are Drs. Rosenblum, Dugar, Burnett, Clader, and McKittrick. All worked for Schering in New Jersey.

67. The '365 patent was originally assigned to Schering Corporation of Kenilworth, N.J. In 2012, Merck Sharp & Dohme became the assignee of the '365 patent by means of a conveyance from Schering Corporation.

68. The '365 patent states that "the present invention relates to hydroxyl-substituted azetidinones useful as hypocholesterolemic agents in the treatment and prevention of atherosclerosis . . . the invention also related to a process for preparing hydroxyl-substituted azetidinones." It observes that "[a] few azetidinones have been reported as being useful in lowering cholesterol and/or in inhibiting the formation of cholesterol-containing lesions in mammalian arterial walls," citing U.S. Patent No. 4,983,594; Ran, *Indian J. Chem.* (1990); European Patent Publication No. 264,231; European Patent No. 199,630; and European Patent Application No. 337,549.

69. The summary of the invention describes hypocholesterolemic compounds of formula I or a pharmaceutically acceptable salt of those compounds. It also states that the invention "relates to" all of the following:

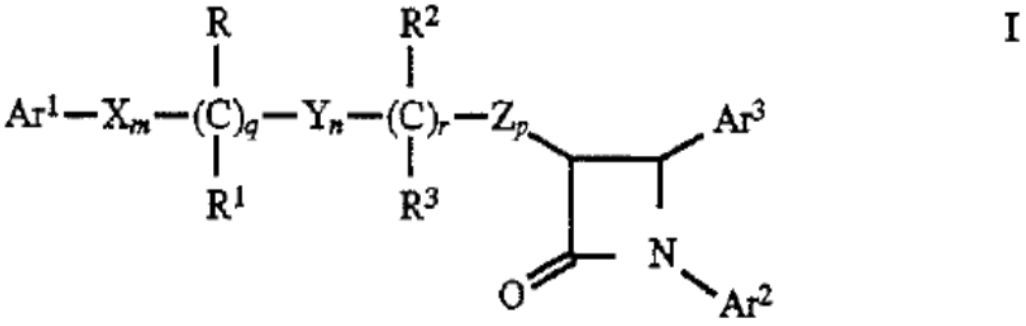
- "[A] method of lowering the serum cholesterol level in a mammal in need of such treatment comprising administering an effective amount of a compound of formula I,"

- "[A] pharmaceutical composition comprising a serum cholesterol lowering effective amount of a compounds of formula I in a pharmaceutically acceptable carrier;"

- "[T]he use of a hydroxyl-substituted azetidinone cholesterol absorption inhibitor of formula I for combined use with a cholesterol biosynthesis inhibitors [e.g., statins] … to treat or prevent atherosclerosis or to reduce plasma cholesterol levels;" and

- "[A] process for preparing certain compounds of formula I comprising [five specific steps]."

**Figure 7. Hypocholesterolemic Compounds of Formula I**




I

70. The specification confirms that the invention includes both enantiomers and racemic mixtures, and that one enantiomer may lead to greater cholesterol inhibition than another: "all isomers, including enantiomers . . . are contemplated as being part of this invention . . . including racemic mixtures." "Isomers can be prepared using conventional techniques, either by reacting chiral starting materials or by separating isomers of a compounds of formula I." "Those skilled in the art will appreciate that for some compounds of formula I, one isomer will show greater pharmacological activity than another isomer."

71. The specification notes that compounds of the invention can exist in "pharmaceutically acceptable" salt forms, identifies at least two dozen salt forms, and describes how to prepare salt forms.

72. The specification notes that "Compounds of formula I can be prepared by known methods, for example those described below and in WO93/02048," and then describes several methods of preparation. It then discloses that many, if not all, of the "starting compounds" used are "either commercially available or well known in the art and can be prepared via known methods."

73. The specification notes: "We have found that the compounds of this invention lower serum lipid levels, in particular serum cholesterol levels. Compounds of this invention have been found to inhibit the intestinal absorption of cholesterol and to significantly reduce the formation of liver cholesteryl (sic) esters in animal models. Thus, compounds of this invention are hypocholesterolemic agents by virtue of their ability to inhibit the intestinal absorption and/or esterification of cholesterol; they are, therefore, useful in the treatment and prevention of atherosclerosis in mammals; in particular in humans." It goes on to describe the procedure used to determine the in vivo activity of the compounds of formula I, using the "hyperlipidemic Hamster."

74. The '365 patent has four claims. All four claims claim a process of preparing a compound of formula I. Claims 1 and 3 are independent claims; Claims 2 and 4 depend on claims 1 and 3, respectively.

75. The '365 patent expired on May 20, 2014.

**(4) Late 1997: Merck files a fifth patent application addressing azetidinones, this one addressing combination use with statins.**

76. On October 14, 1997, Merck filed U.S. Patent Application 953,825 – titled "combinations of hydroxyl-substituted azetidinone compounds and HMG CoA reductase inhibitors" – as a continuation-in-part of the '751 application.

**(5) Mid-1998: Merck obtains a second azetidinone patent covering compounds, a composition, and a method of treating atherosclerosis (the '115 patent).**

77. On June 16, 1998, the '751 application issued as U.S. Patent No. 5,767,115. The '115 patent had nine claims. Claims 1-7 claim compounds, claim 8 claims a pharmaceutical composition for the treatment or prevention of atherosclerosis (or for the reduction of plasma cholesterol levels), and claim 9 covers a method of treating or preventing atherosclerosis (or reducing plasma cholesterol levels) comprising administering to a mammal in need of such treatment an effective amount of a compound of claim 1.

78. Ezetimibe (the active ingredient in Zetia) is within the scope of claims 1-3, 5, and 7 of the '115 patent. Ezetimibe is designated "6A" and is described in Example 6 at column 31, lines 1-10 of the specification and in claim 7 at column 40, lines 19-21.

79. According to Merck, the '115 patent expired on June 16, 2015.

**(6) Late 1998: Merck obtains a third azetidinone patent for use in combination with statins (the '966 patent).**

80. On December 9, 1998, the '825 application issued as U.S. Patent No. 5,846,966.

81. All claims in the '966 patent refer to a hydroxyl-substituted azetidinone used *in combination with* an HMG CoA reductase inhibitor – i.e., a statin. Claim 1 refers to hydroxyl substituted azetidinone compounds used in combination, claims 2-5 refer to compositions of those compounds used in combination, and claim 6 refers to methods of treating or preventing atherosclerosis or reducing plasma cholesterol levels in combination with statins. Claim 8 explicitly refers to simvastatin (the active ingredient in Merck's Zocor) and atorvastatin (the active ingredient in Pfizer's Lipitor).

**D. 2000: Merck asks the PTO to reissue the '115 patent with new ezetimibe claims.**

82. In early 2000, Merck – including Schering Corporation – was preparing a New Drug Application for the drug product that came to be known as Zetia. Merck closely reviewed

the existing patent portfolio, knowing, as all sophisticated pharmaceutical manufacturers do, that the FDA would require them to identify the patents that claim the Zetia product (or a method of using it) by listing them in the Orange Book.

83. On June 15, 2000, Merck filed Reissue Application No. 09/594,996, asking the PTO to reissue the '115 patent. In preliminary remarks, Merck stated that the reissue application was filed "to correct an error concerning the failure to appreciate the full scope of the invention by not including claims of narrower scope directed to one of the most preferred compounds disclosed in the specification," namely, ezetimibe (described as 1-(4-fluoro[phenyl)-3(R)-[3(S)-(4 fluorophenyl)-3-hydroxypropyl)]-4(S)-(4-hydroxyphenyl)-2-azetidinone). Merck proposed adding claims 10-13, claiming the ezetimibe compound (in both prose and graphic form, claims 10 and 11), a pharmaceutical composition for the treatment or prevention of atherosclerosis or the reduction of plasma cholesterol levels (claim 12), a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels (claim 13), and a method of use thereof.

84. Merck submitted a declaration in support of reissue signed by James R. Nelson, Staff Vice President and Associate General Counsel, Patents & Trademarks at Schering-Plough Corporation and Vice President at Schering Corporation. Nelson described the error as "the failure to include a specific claim to one of the most preferred compounds."

### E. 2001-2002: Merck obtains approval for Zetia, the RE'721 patent, and a corresponding 16-month patent term extension.

#### (1) 2001: Merck files an NDA for Zetia.

85. On December 27, 2001, while the application for reissue was pending, Merck submitted NDA 21445 seeking FDA approval to market ezetimibe tablets in the United States under the brand name Zetia for the treatment of hypercholesterolemia.

86. The NDA sponsor is sometimes identified as Merck/Schering-Plough Pharmaceuticals and sometimes as MSP Singapore Company LLC. The proposed labeling

submitted with the NDA is marked "COPYRIGHT Merck/Schering-Plough Pharmaceuticals." In correspondence, Schering Corporation is identified as the U.S. agent for MSP Singapore. During its review, the FDA corresponded with Schering's Regulatory Affairs department, including with Joseph F. Lamendola, Jack Scannelli, and Beth DiDomenico.

87. The FDA's review of Zetia took about ten months. Merck later sought and obtained a patent term extension for the period of time encompassed by this regulatory review (discussed below).

**(2) 2002: The PTO reissues the '115 patent as the RE'721 patent.**

88. On May 28, 2002, the RE'966 application issued as U.S. Patent No. RE37,721 with new claims 10-13. These included the compound ezetimibe (claims 10-11), a composition of ezetimibe (claim 12), and a method of using ezetimibe to treat or prevent atherosclerosis or reduce plasma cholesterol levels (claims 13).

**(3) 2002: The FDA approves Zetia.**

89. On October 25, 2002, the FDA approved the Zetia NDA and granted it a five-year New Chemical Entity ("NCE") exclusivity. Merck launched Zetia later that month. Zetia quickly became a steady source of profits for Merck, with annual U.S. sales of about $1 billion in 2010 and $2.6 billion by 2016.

90. The originally approved labeling reflects that Zetia is manufactured for Merck/Schering-Plough Pharmaceuticals by Schering Corporation *or* Merck & Co., Inc.

**(4) 2002: Merck seeks a 16-month patent term extension for the RE'721 patent.**

91. On December 12, 2002, Merck – via James R. Nelson of Schering – requested an extension of the patent term of the RE'721 patent based on the duration of the FDA's review of the Zetia NDA (pursuant to 35 U.S.C. § 156 and 37 C.F.R. §§ 1.710-1.791). Merck asked that an additional 497 days of patent term be added.

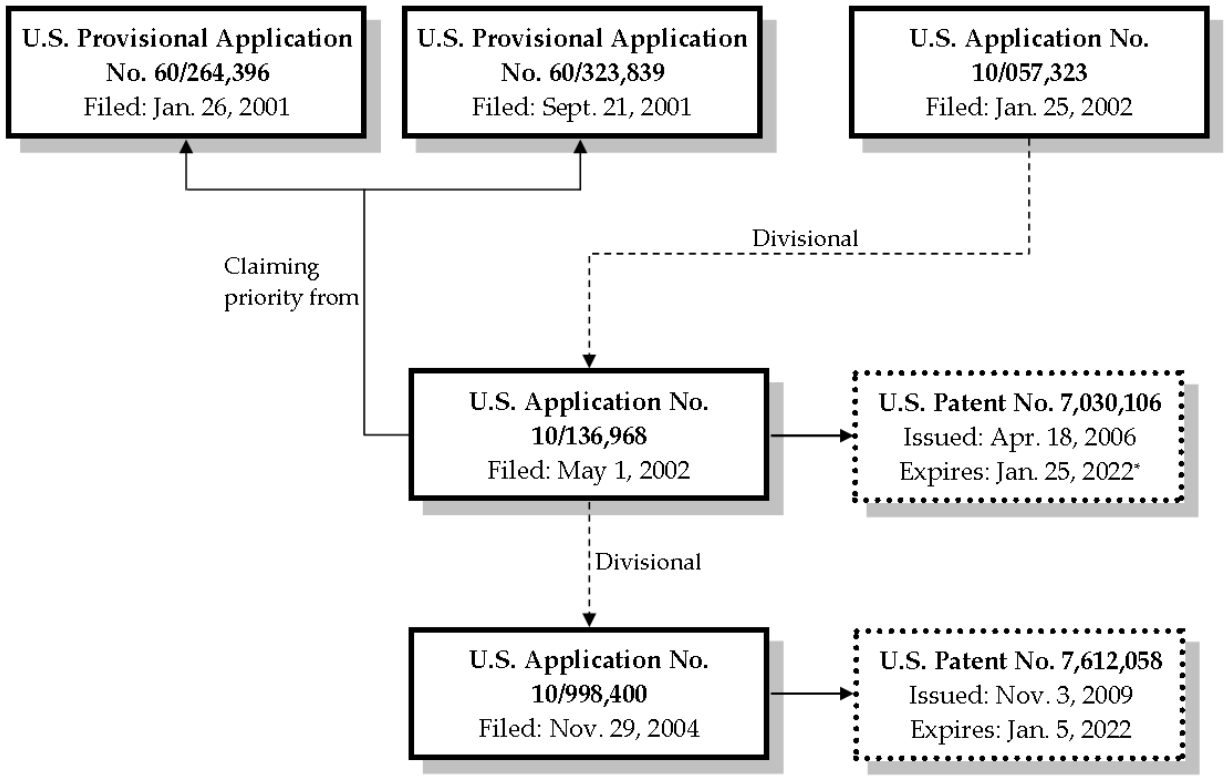
92. Ultimately, on January 17, 2006, the RE'721 patent was extended through October 25, 2016. The PTO (in reliance on information obtained from Schering and confirmed by the FDA) determined that the RE'721 patent was eligible for a patent term extension of 497 days. The PTO noted that the period of FDA review was 948 days but noted that 35 U.S.C. § 156(c)(3) operates to limit the term of the extension: "the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years." With the extension, the RE'721 patent was set to expire on October 25, 2016 (fourteen years from the date of FDA approval).

**F. 2006: Merck obtains its first "sterol non-absorption" patent (the '106 patent).**

93. After Merck filed its NDA, but before it was approved, Merck sought to extend its patent protection for Zetia. Merck filed a series of patent applications relating to compounds that inhibit sterol absorption and methods for treating specific conditions with those compounds. Two issued as patents (the '106 patent and the '058 patent). For shorthand, we refer to this family of patents as "the sterol non-absorption" applications and patents.

94. The sterol non-absorption applications did not claim priority to, or derive from, the azetidinone applications. Nor did they share any inventors.

**Figure 8. The Sterol Non-Absorption Patents**




*All expiration dates are calculated without pediatric exclusivity extensions.

95. On April 18, 2006, Merck's Application No. 10/136,968[6] issued as U.S. Patent No. 7,030,106. The '106 patent was Merck's first sterol non-absorption patent. It has two claims. The inventor is Wing-Kee Philip Cho of Princeton, NJ. The assignee was originally Schering Corporation.

96. According to Merck, the '106 patent originally was set to expire on January 25, 2022, but, with a pediatric extension, is now set to expire on July 25, 2022.

[6] On January 25, 2002, Merck filed Utility Application No. 10/057,323. The '323 application claimed priority to two provisional applications, filed on January 26, 2001 and September 21, 2001, respectively. It did not claim priority to, nor was it related to, the azetidinone patents described above. On May 1, 2002, Merck filed Application No. 10/136,968 as a divisional of the '323 application. The primary examiner was San-Ming Hui. The '323 and '968 applications purported to address compounds and compositions that inhibited sterol absorption.

97. The ’106 patent specification says that “the present invention relates to therapeutic combinations of peroxisome proliferator-activated receptor (PPAR) activator(s) *and* sterol absorption inhibitor(s) for treating vascular conditions (including atherosclerosis)” (emphasis added).

98. But neither of the claims in the ’106 patent refers to combination use. Both claim pharmaceutical compositions of ezetimibe that were earlier disclosed in the RE’721 patent.[7] Given this and other earlier disclosures, the ’106 patent is, and clearly was at the time of its issuance, invalid as obvious and/or for obviousness-type double patenting.

99. By this time, Merck/Schering had listed in the Orange Book the RE’721 azetidinone patent, the ’966 combination-with-statins patent, and the ’106 sterol non-absorption patent. The ‘365 process patent was not listed in the Orange Book, likely because process patents – unlike product or method of use patents – are not eligible for listing.

**G. 2006: Glenmark files the first ANDA for generic Zetia.**

100. On or about October 25, 2006, generic drug manufacturer Glenmark filed ANDA 78-560, seeking FDA approval to market an AB-rated generic version of Zetia. That day was the first day on which applicants to market generic versions of Zetia were permitted to file an ANDA for that product—one year before expiration of Merck’s five-year NCE exclusivity—and then only if the ANDA included a paragraph IV certification.

[7] The compound represented in Formula II of claims 1 and 2 of the ’106 patent is ezetimibe. The table in claims 1 and 2 describing the composition lists lactose monohydrate (a sugar); microcrystalline cellulose (a starch); povidone (a disintegrant); crosscarmellose sodium (a dissolving agent); sodium lauryl sulfate (a foaming agent); and magnesium stearate (a release agent). All are conventional excipients and additives. The RE’721 specification explicitly refers to compositions made using conventional excipients and additives and conventional techniques, including “non-toxic compatible fillers, binders, disintegrants, buffers, preservatives, antioxidants, lubricants, flavorings, thickeners, coloring agents, emulsifiers, and the like.”

101. Merck's new chemical entity exclusivity expired on October 25, 2007, one year from the date Glenmark filed. Glenmark could not come to market until after that exclusivity expired.

102. Glenmark's ANDA included a paragraph IV certification to all of the patents then listed in the Orange Book: the RE'721 azetidinone patent, the '966 combination-with-statins patent, and the '106 sterol non-absorption patent.[8]

**H. 2007-2008: Merck sues first-filer Glenmark; Glenmark counterclaims.**

**(1) Early 2007: Merck sues Glenmark for infringing the RE'721 patent (only).**

103. On or about February 9, 2007, Glenmark notified Merck of its ANDA filing and provided a detailed account of why the patents were invalid, unenforceable, and not infringed by Glenmark's ANDA product ("Glenmark's paragraph IV letter").

104. On March 22, 2007, Merck[9] sued Glenmark in the District of New Jersey. Merck alleged that Glenmark's ANDA infringed the RE'721 patent (only).

105. Merck did not sue Glenmark, in this suit or any other, for infringing the two other Orange-Book-listed patents, the '966 and the '106 patents. Merck apparently did not believe that it could realistically expect to win a lawsuit asserting that Glenmark's generic ezetimibe product would infringe the '966 combination-with-statins azetidinone patent or the '106 sterol nonabsorption patent because those patents were inapplicable, invalid, or not infringed. Glenmark's product did not include a statin. And the unasserted '106 patent was, and is, invalid as obvious (as described above).

[8] Because the '365 process patent was not listed in the Orange Book, Glenmark did not need to certify to it in its ANDA.

[9] In this litigation, defendants Schering Corporation and MSP Singapore Company LLC referred to themselves collectively as "Schering." Giant Eagle refers to them here as "Merck" instead.

106. Under the Hatch-Waxman Act, Merck's filing of the RE'721 lawsuit – irrespective of its prospects of success – triggered a 30-month stay, running from the date Glenmark notified Merck of its paragraph IV letter. This stay prevented the FDA from granting final approval of Glenmark's ANDA until the earlier of (i) the expiration of the thirty-month stay, or (ii) entry of a final judgment that the RE'721 patent was invalid, unenforceable, and/or not infringed. [10]

107. Glenmark represented in a pleading early on that "[t]he amount at issue in this case is at least $1 billion, representing the anticipated sales by Glenmark of its generic product (and the corresponding loss of sales by [Merck])."

**(2) Spring 2007: Glenmark counterclaims, alleging the RE'721 patent is invalid and unenforceable.**

108. On May 23, 2007, Glenmark answered, listed its affirmative defenses, and counterclaimed.[11] Glenmark sought a declaratory judgment that the RE'721 patent was invalid and/or unenforceable. Glenmark asserted that the RE'721 patent was invalid for double patenting, anticipation, obviousness, lack of enablement, and inventorship issues. Glenmark also asserted that the RE'721 patent was unenforceable due to inequitable conduct and that Merck was estopped or precluded from asserting infringement by reasons of actions taken and statements made to the PTO during prosecution of the application(s) that led to the RE'721 patent.[12] Glenmark refined these arguments as the litigation progressed.

[10] Thirty months from the date Glenmark sent its paragraph IV certification is August 9, 2009. At one point during the litigation, Merck asserted that the 30-month stay expired on October 25, 2010. Giant Eagle alleges here that generics would have entered as early as December 6, 2011, so the day on which the stay expired – under either interpretation – is before alleged generic entry.

[11] Glenmark filed a corrected answer on June 7, 2007. On March 10, 2008, Glenmark filed a first amended answer and counterclaim.

[12] In Glenmark's first amended answer and counterclaim, filed on March 10, 2008, it added a claim asserting that the 497-day patent term extension Merck received for the RE'721 patent was invalid.

109. *Invalid for inherent anticipation.* Glenmark argued that at least two compounds claimed in the RE'721 patent are inherent metabolites of a hypercholesterolemic compound (SCH48461) disclosed in an earlier Schering patent application. Merck had disclosed two compounds claimed in the RE'721 patent in an earlier patent application: International Application No. PCT/US92/05972, filed on July 21, 1992 and published on February 4, 1993 as WO 93/02048 (the "PCT'048 publication").[13] Upon ingestion, at least one of these earlier disclosed compounds, SCH48461 (disclosed as Example 9), is metabolized to form two hydroxyl-substituted compounds that are both claimed in the RE'721 patent. These metabolites inherently anticipate the claims of the RE'721 patent.

110. Under the doctrine of inherent anticipation, "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference."[14]

111. Merck and Schering were well aware of the doctrine of inherent anticipation. That doctrine featured prominently in a case Schering brought against Geneva Pharmaceuticals for allegedly infringing a patent for the prescription drug Claritin. There, on August 8, 2002, the district court concluded that "the natural, inevitable production of metabolic DCL upon human ingestion of loratadine, although not fully appreciated by persons of ordinary skill in that field until more recently . . . , demonstrates that this process is an inherent characteristic or functioning of the use of loratadine, the subject of the '233 patent. Therefore, that patent inherently anticipates Claims 1 and 3 of the '716 patent, rendering them invalid." The district court

[13] The named co-inventors of PCT'048 are Duane A. Burnett, John W. Clader, Tiruvettipuram K. Thiruvengadem, Chou-Hong Tann, and Junning Lee. Burnett and Clader are named as co-inventors of the '721 patent. The publication date of the PCT'048 predates all applications to which the RE'721 claims priority.

[14] *Schering Corp. v. Geneva Pharm., Inc*., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citing *Cont'l Can Co. v. Monsanto Co*., 948 F.2d 1264, 1268 (Fed. Cir. 1991)), *reh'g denied*, 348 F.3d 992 (2003).

observed that "this is not a new doctrine," and cited cases from the 1980s and 90s. The district court also noted that Schering's policy arguments to the contrary were "not persuasive" and that the Patent and Trademark Appeals Board's opinions Schering cited in support of its arguments that inherency by anticipation did not apply were "not consistent with the Federal Circuit law." The Federal Circuit later affirmed.

112. *Inequitable conduct for failure to disclose inherency.* Glenmark argued that Merck committed inequitable conduct during prosecution of the RE'721 patent by not disclosing the inherency of these metabolites to the PTO. Merck did not do so before the RE'721 patent issued, nor did it do so in any post-issuance communications with the PTO about the RE'721 patent.[15] Inequitable conduct is the atomic bomb of patent law; when found, the entire patent becomes invalid and/or unenforceable.

113. Glenmark identified several publications describing the work that the Merck scientists did to investigate compound SCH48461, its metabolites and metabolite-like analogues, that supported its inherency argument – many authored or reviewed by Merck scientists who were also inventors of the RE'721. Merck never disclosed these publications to the PTO during prosecution of the RE'721 patent. Glenmark argued that these publications would have been

[15] The RE'721 patent issued on May 28, 2002. The district court *Schering v. Geneva* opinion issued on August 2, 2002. On August 14, 2002, Schering filed a Request for Certificate of Correction for the RE'721 patent with the PTO, seeking to correct the priority information recited in the RE'721 patent (likely to ensure that it was treated as an application filed under 35 U.S.C. § 371 and therefore had a later expiration date than the '365 and '966 patents). On December 12, 2002, Schering filed a Request for Patent Term Extension with the PTO. On August 1, 2003, the Federal Circuit affirmed the district court's inherency decision. Schering's request for patent term extension was not resolved until August 29, 2006. Between May 28, 2002, and the conclusion of the patent term extension in 2006, Schering never mentioned inherency or either *Schering v. Geneva* decision in any of its communications with the PTO about the RE'721 patent.

material to the PTO when examining the RE'721 patent. That Merck withheld them, and key information they contained, reflects deceptive intent.[16] These publications included:

- Margaret Van Heek et al., Abstract, *Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible* in Vivo *Mechanism of Action for their Inhibition of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Van Heek 1995 abstract");

- Harry R. Davis, Jr. et al., Abstract, *The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA Reductase Inhibitors*," Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Davis 1995 abstract");

- Stuart B. Rosenblum et al., Abstract, *Discovery of SCH 58235: A Potent Orally Active Inhibitor of Cholesterol Absorption*, Baylor College of Medicine XII International Symposium on Drugs Affecting Lipid Metabolism (Nov. 7-10, 1995) (the "Rosenblum 1995 abstract");

- John W. Clader et al., *2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the Heterocyclic Nucleus*, 39 J. Med. Chem. 3684 (1996) (the "Clader 1996 publication");[52]

- Sundeep Dugar et al., *Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079, an Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461*, 11 Bioorganic & Med. Chem. Letters 1271 (1996) (the "Dugar 1996 publication");

- Margaret Van Heek et al., *In Vivo Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH 48461*, 283 J. Pharmacology & Experimental Therapeutics 157 (1997) (the "Van Heek 1997 publication");[53]

- Stuart B. Rosenblum et al., *Discovery of 1-(4-Fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH58235): A Designed, Potent, Orally Active Inhibitor of Cholesterol Absorption*, 41 J. Med. Chem. 973 (1998) (the "Rosenblum 1998 publication").[17]

[16] Rather than repeat the details of Glenmark's discussion of these publications here, Giant Eagle incorporates by reference ¶¶ 30-171 of Glenmark's First Amended Answer and Counterclaims (*Schering Corp. v. Glenmark Pharm. Inc.*, USA, No. 07-cv-01334 (D.N.J. Mar. 10, 2008), ECF No. 54).

[17] Submitted October 16, 1997.

114. *Inequitable conduct re patent term extension.* Glenmark argued that Merck further committed inequitable conduct when seeking the RE'721 patent term extension, by not disclosing that at least some claims were invalid due to inherent anticipation. Merck sought to extend the term of the RE'721 patent claims after *Schering v. Geneva* was decided, knowing that claims it sought to extend were invalid under the doctrine of inherent anticipation.

115. *Invalidity for lack of enablement.* Glenmark argued that the RE'721 patent does not teach one skilled in the art how to use ezetimibe to prevent atherosclerosis without further experimentation, which renders claims invalid for lack of enablement.

116. To be enabled, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. Articles published after a patent application's filing date *can* establish a lack of enablement.

117. *Failure to name inventors.* Glenmark argued that Merck may have failed to name all inventors and took discovery on the issue. On May 10, 2006, the industry group Pharmaceutical Research and Manufacturers of America ("PhRMA") presented the Discoverers Award for contributions to the discovery of ezetimibe to three individuals: Harry R. Davis, Jr., Dr. Margaret Van Heek, and Kevin B. Alton. Merck had nominated all. None were listed as inventors on the RE'721 patent.

118. *Lack of proper reissue.* Glenmark argued that reissue was improper, and thus the reissued claims were invalid, for failure to identify an error in the '115 patent of the type that may be properly corrected through reissue.

119. *Invalidity for obviousness-type double patenting.* Glenmark argued that the subject matter claimed in the RE'721 patent was not patentably distinct from matter claimed in Merck's earlier issued (and earlier expiring) '365 patent. As a result, at least some claims of the RE'721 patent were alleged to be invalid for obviousness-type double patenting.

**I. Spring 2009: Glenmark receives tentative approval, and Merck receives new regulatory exclusivities.**

120. On April 24, 2009, the FDA gave tentative approval to Glenmark's Zetia ANDA. It did so within the 30-months allotted by statute, and so secured Glenmark's first-filer 180-day exclusivity.

121. At the time Glenmark received tentative approval, the 30-month stay prevented Glenmark from launching.

122. In 2009, the FDA listed a new exclusivity in the Orange Book – for adding pediatric information to the label – which expired on June 5, 2011. The FDA also added pediatric exclusivities to all listed patents and exclusivities, which expired on December 6, 2011.

**J. Summer 2009: Glenmark seeks partial summary judgment on two discrete legal issues**.

123. In separate motions for partial summary judgment in July of 2009, Glenmark raised two discrete legal issues as to which it did not believe there to be any disputed issues of facts. At that time, trial was scheduled for May of 2010.

124. In the first motion, Glenmark argued that the RE'721 patent was invalid for Merck's failure to identify an error of the type that may be properly corrected in reissue. Glenmark argued that the '115 patent was not, as issued, wholly or partly invalid, and that therefore it could not be properly reissued under 35 U.S.C. § 251.

125. In the second motion, Glenmark argued that 12 of the 13 claims in the RE'721 patent were invalid by reason of obviousness-type double patenting, in light of Merck's earlier issued '365 patent.

126. Neither Glenmark nor Merck moved for summary judgment on any of the other issues or arguments listed above (e.g., inherent anticipation, inequitable conduct, lack of enablement, or failure to name inventors). From the fact that Glenmark did not move for

summary judgment on other grounds one can infer that Glenmark (1) preferred to present its other arguments to the finder of fact at trial or (2) believed there to be disputed issues of fact between the parties that would prevent its arguments from being conclusively resolved at the summary judgment stage.

**K. Fall 2009: Merck obtains the second sterol absorption patent (the '058 patent).**

127. On November 3, 2009, while the Glenmark summary judgment motions were pending, Merck's Application No. 10/998,400[18] issued as U.S. Patent No. 7,612,058, Merck's second sterol non-absorption patent.

128. The '058 patent is subject to a terminal disclaimer. According to Merck, it originally was set to expire on January 25, 2022, and with a pediatric extension is set to expire on July 25, 2022.

129. The '058 patent includes 10 claims. All cover methods of treating conditions associated with high cholesterol (e.g., atherosclerosis, diabetes, obesity) comprising administering a pharmaceutical composition consisting of the same compound and routine pharmaceutical additives described in the '106 patent (Formula II, ezetimibe). The '058 patent was at the time it was issued, and at all times thereafter, invalid for the same reasons as the '106 sterol non-absorption patent. Like the '106 patent, the named inventor is Philip Wing-Kee Cho.

**L. Spring 2010: Par becomes Glenmark's partner in generic Zetia.**

130. On April 30, 2010, Glenmark and Par entered into a Marketing and Distribution Agreement (the "Glenmark/Par Distribution Agreement") whereby Glenmark appointed Par to be the exclusive distributor to market, distribute and sell Glenmark's generic Zetia in the United

[18] On November 29, 2004, Schering filed Application No. 10/998,400 as a divisional of the '968 application, seeking another inhibition of sterol absorption patent. The primary examiner was again San-Ming Hui.

States. In exchange for, among other things, an upfront payment to Glenmark and a promise to share the net profits from the sale of the drug between Par and Glenmark, Glenmark granted Par the exclusive right to distribute its generic Zetia in the United States.

131. The Glenmark/Par Distribution Agreement establishes that Glenmark provided Par "all documents or materials in its possession or control" relating to the ANDA litigation between Merck and Glenmark. The Agreement required Par and Glenmark to "jointly" make "all material decisions" in the Merck-Glenmark patent infringement litigation or any other litigation involving generic Zetia. Specifically, section 9.2.2 of the Glenmark/Par Distribution Agreement, entitled "Decisions," provided:

> 9.2.2 Decisions. Glenmark shall keep Par reasonably informed regarding material developments with respect to any Litigation. Glenmark shall continue to control the defense of the Litigation, except that all material decisions with respect to the Litigation shall be made jointly by Glenmark and Par; provided, however, that if the Parties fail to promptly agree upon a course of action, Glenmark's decision shall control any Litigation as well as any settlements thereof. Glenmark and Par, to the extent necessary to protect and preserve the attorney-client privilege between Glenmark and its counsel, shall enter into a common interest and/or joint defense agreement.

132. Under the terms of the Glenmark/Par Distribution Agreement, Glenmark could not settle its lawsuit with Merck without Par's "written consent." And, if any such settlement were to occur, Glenmark was required to share any proceeds with Par. Pursuant to this provision, Par gave its written consent to the unlawful settlement agreement between Merck and Glenmark.

133. The Glenmark/Par Distribution Agreement also required Par to consult with Glenmark regarding marketing, pricing, and distribution decisions, and explicitly established a Steering Committee comprised of "an equal number of duly qualified representatives of Par and Glenmark . . . with the necessary authority to deal with and make decisions concerning the

matters within the Steering Committee's authority." The Steering Committee's responsibilities included:

a. "advise on the overall strategy for the marketing of the Product [generic Zetia];

b. "review and advise on the marketing plan";

c. "monitor the activities and performance of Par related to the marketing plan";

d. "review and advise on decisions in connection with the marketing plan";

e. "review and advise on major amendments to the marketing plans, including without limitation, with respect to timelines and budgets";

f. "discuss pre-Launch marketing plans and strategies (including the estimated Launch Date)"; and

g. "review and advise on life cycle management plans for the Product [generic Zetia] after the Product has been launched or has been actively planned for Launch."

134. The Glenmark/Par Distribution Agreement required Glenmark and Par to establish the Steering Committee within 30 days of the Agreement's execution, and to meet a minimum of twice a year. It also provided that the Steering Committee would be chaired by a Glenmark representative prior to "pre-Launch commercialization planning" but thereafter by a representative of Par. On information and belief, under the Agreement, Par became Glenmark's partner in the profits made from the sale of Glenmark's generic Zetia in the United States, as well as the Merck-Glenmark ANDA litigation, any settlement of that litigation, and any proceeds or benefits of such a settlement.

135. Par performed under the Glenmark/Par Distribution Agreement by consenting to the unlawful settlement agreement between Merck and Glenmark, by distributing Glenmark's generic Zetia in the United States, and by furthering the purposes of the unlawful conspiracy. Par benefited from the conspiracy because the profits it retained from the sale of Glenmark's

generic Zetia were higher than they otherwise would have been as a result of the absence of competition from a Merck authorized generic.

**M. Summer 2010: Merck and Glenmark/Par settle with a reverse payment.**

**(1) The Court sends Glenmark's double-patenting argument to trial.**

136. On April 19, 2010, the Honorable Jose L. Linares of the U.S. District Court for the District of New Jersey issued opinions addressing each of Glenmark's motions for partial summary judgment. First, the court granted Glenmark's motion on invalidity, agreeing with Glenmark that reissuance of the '115 patent had been improper because Merck had failed to identify the kind of purported error that can be corrected in reissue. This functionally threw out claims 10-13, which claimed ezetimibe expressly and had been added in reissue. Merck moved for reconsideration of this order on April 30, 2010.

137. On the same day, the court denied Glenmark's second motion for partial summary judgment (obviousness-type double patenting), concluding that disputed issues of fact as to whether, at the time of the '365 patent, alternative processes for making the claimed azetidinone compounds existed. The court did not hold that there was no double patenting. Rather, the court simply concluded that the issue of double patenting should be resolved by the finder of fact at trial, based on a full evidentiary record.

**(2) Two days before trial, Merck and Glenmark/Par agreed to settle by providing a reverse payment to Glenmark/Par.**

138. Trial was scheduled to begin on May 12, 2010. At issue were Glenmark's affirmative defenses and counterclaims, including its assertion that claims 1 through 9 were unenforceable because of Merck's intentional failure to disclose to the PTO either (1) that compounds claimed in the RE'721 were naturally occurring metabolites of SCH46481 (and therefore inherently anticipated by earlier disclosures), or (2) the disqualifying prior art publications by Merck's own scientists that had been hidden from the PTO.

139. On May 10, 2010, two days before the scheduled start of trial, Merck and Glenmark entered into an agreement that settled the patent infringement lawsuit and unlawfully allocated the market for ezetimibe.

140. Merck and Glenmark agreed to entry of a consent judgment. In order to ensure there were no adverse rulings concerning the RE'721 patent as a result of the litigation, a condition of the settlement included that the parties seek to have the court vacate its partial summary judgment invalidating claims 10-13 for improper reissue. The parties gave the court a proposed order, along with the consent judgment vacating the partial summary judgment order on claims 10-13. That proposed order makes reference to the fact that the ruling of the Board of Patent Appeals and Interferences in *Ex parte Tanaka*, on which the Court based its ruling invalidating claims 10-13, had been docketed for appeal.

141. The proceedings on entry of the consent judgment revealed that the parties had agreed that, subject to certain unrevealed caveats, Glenmark would not enter the market with its generic Zetia product until December 12, 2016.

142. As noted above, the Glenmark/Par Distribution Agreement prohibited Glenmark from settling with Merck absent Par's express written consent, which Par provided. The settlement agreement also identified Par as the distributor of "Glenmark Product [generic Zetia] in the United States on or after the [unlawfully agreed-to] Entry Date."

143. Par knowingly and voluntarily agreed to the terms of the unlawful settlement and authorized its execution by Glenmark. By operation of the Glenmark/Par Distribution Agreement, Par and Glenmark were partners with one another in the distribution of Glenmark's generic Zetia and both conspired with Merck to delay the entry of generic ezetimibe and allocate the market for generic ezetimibe in the United States.

144. Although the consent judgment made reference to the settlement agreement, the agreement was not docketed in the court record, and the parties did not publicly reveal any of the remaining terms of that agreement at the time of the settlement. Nor have the other terms of that agreement ever been made public.

145. On information and belief, the settlement agreement confirms that, as a *quid pro quo* for Glenmark's agreement to drop its patent challenge and delay market entry for over five years, Merck promised not to launch a competing authorized generic version of Zetia during Glenmark's eventual 180-day exclusivity period (the "no-AG agreement"). Under sections 5.2 and 5.4 of the settlement agreement, Glenmark/Par agreed not to launch generic ezetimibe until December 12, 2016 (or earlier under certain circumstances). Under section 5.3 of the unlawful settlement agreement, Merck agreed not to launch an authorized generic in competition with Glenmark/Par "[d]uring any period of exclusivity to which Glenmark is entitled under 21 U.S.C. § 355(j)(5)(B)(iv) [180-day exclusivity], and through the expiration of [Merck's] rights under the '721 Patent and Ezetimibe Pediatric Exclusivity." As it turned out, Glenmark/Par was permitted to launch generic ezetimibe on December 12, 2016, Merck's rights under the '721 Patent (including pediatric exclusivity) expired on April 25, 2017, and Glenmark's 180-day exclusivity expired on June 10, 2017.

146. On information and belief, internal documents of Merck and Glenmark produced in discovery in related antitrust cases demonstrate that both companies understood the settlement agreement to prohibit Merck's launch of an AG for some period of time after Glenmark/Par's entry, although there was a disagreement about when the no-AG commitment expired. Merck implausibly interpreted section 5.3 of the settlement agreement to permit the launch of an AG upon the conclusion of Glenmark's 180-day exclusivity *or* the expiration of Merck's rights under the '721 Patent, whichever came earlier, while Glenmark/Par interpreted section 5.3 much more

naturally to permit the launch of an AG upon the conclusion of Glenmark's 180-day exclusivity *and* the expiration of Merck's patent rights, whichever came later. Thus, Merck took the position that it was permitted to launch an AG when its patent rights expired on April 25, 2017, while Glenmark took the position that Merck was not permitted to launch an AG until June 10, 2017.

147. Glenmark also recognized that section 5.3 of the settlement agreement prohibited Merck from launching an AG for some period of time beginning with Glenmark/Par's entry.

148. Even after executing the settlement agreement with Glenmark, Merck continued to plan for the launch of an authorized generic of Zetia in 2017.

149. In October 2016, Merck entered into a Supply and Distribution Agreement with Prasco, an experienced distributor of authorized generics. On information and belief, Merck and Prasco eventually settled on a launch date of approximately three weeks prior to the expiration of Glenmark's 180-day exclusivity and the entry of additional generics. Merck and Prasco concluded that an AG was economically viable even if were launched only three weeks prior to the entry of additional generics.

150. In the months leading up to execution of the Supply and Distribution Agreement with Prasco, Merck recognized that its interpretation of section 5.3 of the settlement agreement was likely to be challenged. Accordingly, an in-house lawyer for Merck wrote to Glenmark on June 8, 2016, stating its interpretation of section 5.3—*i.e.*, that Merck's agreement to refrain from introducing an AG ended on April 25, 2017.

151. Glenmark disputed Merck's interpretation of section 5.3. Representatives of Merck met with representatives of Glenmark and Par on August 11, 2016, in an effort to resolve the dispute. On information and belief, on August 30, 2016, Glenmark's Vice President for

Global Intellectual Property wrote to Merck's Senior Vice President and Assistant General Counsel stating that Merck's interpretation of section 5.3 was incorrect.

152. Merck ultimately capitulated to Glenmark/Par's interpretation of their agreement. It concluded that launching an authorized generic on June 10, 2017, was not economically viable and terminated the AG project. It had already shipped product to Prasco, which was returned. Given Merck's recognition that a Zetia AG was economically viable even if it entered the market only three weeks before the entry of additional generics, there is no question that Merck would have launched an AG simultaneously with the launch by Glenmark/Par had it not agreed to refrain from doing so.

153. Given Merck and Glenmark's choice to conceal the terms of their unlawful agreement, the absence of an AG launch for generic Zetia could be publicly learned only at the time that Merck failed to undertake such a launch – late December 2016 and the first six months of 2017. Given the concealment of the confidential settlement agreement, the existence of the no-AG agreement could not have been known until Glenmark launched its generic in 2016 and Merck failed to launch an AG product.

154. The no-AG agreement was a payment to Glenmark and Par from Merck worth substantially more than Glenmark and Par could have earned if they had come to market with generic Zetia in 2011. And, Glenmark/Par could not have obtained a no-AG agreement even had it won the patent infringement litigation. By delaying generic entry for more than five years, and thereby obtaining the no-AG agreement from Merck, Glenmark/Par was ensured six months of exclusive generic sales, free from competition from Merck's authorized generic or any other generic competitors.

155. For Merck, the benefits of the no-AG agreement were enormous. While it would forgo six months of profits on an authorized generic, it would enjoy more than five years of monopoly profits selling much more expensive and profitable branded Zetia.

156. The reverse payment agreement was entered into in May 2010. That agreement delayed Glenmark's generic entry until December 2016. Absent the reverse payment, generic entry would have occurred on or after December 6, 2011, when Merck's last regulatory exclusivity ended. By then, Glenmark would have resolved the RE'721 infringement claims by either winning at trial or settling on competitive terms (without a payment), or it would have launched at risk. And, Merck has never accused Glenmark of infringing any other Orange Book-listed patents covering Zetia.

157. By December 6, 2011, other than the RE'721 patent (addressed below), no other impediments existed to the prompt approval and launch of generic Zetia.

158. First, Glenmark's ANDA had already received FDA tentative approval. In effect, Glenmark had met all preconditions for final FDA approval other than the 30-month stay that Merck's enforcement of the RE'721 triggered against Glenmark.

159. Second, no other patents held by Merck would forestall generic entry. The '966 patent had claims only to combination products, but generic Zetia is not a combination product, and Merck never enforced the '966 patent against Glenmark. The '106 and '058 sterol nonabsorption patents were obvious in light of the RE'721 disclosures, and Merck never enforced those patents against Glenmark. The '365 patent was limited to the narrow processes set out in that patent, and Merck never enforced the '365 patent against Glenmark.

160. Third, no other exclusivity existed after December 5, 2011. Merck's NCE exclusivity expired in 2007. Two other exclusivities – an indication exclusivity I-493 and a

pediatric exclusivity M-54 – were capable of being carved out of any generic label, and in any event had expired by December 5, 2011.

161. As to the RE'721 patent, in the absence of the reverse payment and with Merck and Glenmark/Par acting as lawful, economically rational companies, generic entry would have occurred much sooner than it did. Such earlier entry would have occurred in one of three alternative ways.

162. First, absent the reverse payment, Glenmark/Par and Merck could have settled the litigation, but without a reverse payment, and with an earlier agreed entry date. That agreed entry date would have been based on the merits of Merck's RE'721 infringement claims – claims that had no merit – rather than a payment. As a result, an arms'-length settlement between economically rational, law-abiding companies would have led to an agreed entry date much sooner than December 2016.

163. Second, absent the reverse payment, Glenmark/Par would have won the trial scheduled to start in May 2010. In that trial, a finder of fact would have concluded that (for the reasons described above) Merck failed to prove that Glenmark/Par infringed a valid patent for one or more of the following reasons:

- Merck (through the inventors, agents, and others with a Rule 56 duty) committed inequitable conduct by intentionally and deceptively hiding the fact that the RE'721 claimed compounds that were naturally occurring metabolites of SCH 48461 (and therefore inherently anticipated by its earlier disclosure in PCT'048), which would render the entire RE'721 patent invalid or unenforceable);

- Regardless of whether Merck committed inequitable conduct, the claims of the RE'721 patent were invalid for inherent anticipation; and

- The RE'721 patent was invalid for obviousness-type double patenting over the '365 patent.

164. Having gone to trial and won, Glenmark/Par would have launched generic Zetia soon after a district court ruling in its favor and the expiration of any other, lawful exclusivity.

165. Third, absent the unlawful reverse payment, Glenmark/Par could have launched generic Zetia at risk, prior to a favorable district court decision, recognizing that it would almost surely prevail in the patent trial.

166. Without the large and unjustified payment, several additional generics would have come to market after Glenmark/Par's 180-day exclusivity ended – as early as June 6, 2011, and in any event much earlier than June 12, 2017.

167. In the absence of the unlawful agreement, Merck would have launched its authorized generic version of Zetia at or around the same time that Glenmark launched its generic.

**(3) The value of the agreement to Merck.**

168. With generic entry in December 2011, Merck would have lost at least 80% of its branded sales. But without generic entry, it kept all those sales – and continued to enjoy those branded sales until the end of 2016.

169. Because Glenmark was the first ANDA filer, its agreement not to launch generic Zetia until December 2016 created a bottleneck preventing any other generic company from marketing a generic Zetia product until 180 days after Glenmark/Par launched its generic product. In establishing a bottleneck using Glenmark/Par, Merck maximized the potential for it to maintain its monopoly on Zetia for about five years longer than it otherwise would have. The additional monopoly profits earned by Merck during those five years vastly outweigh the cost of forgoing the sales of an authorized generic. Giant Eagle estimates that Merck enjoyed between $5.7 billion and $8.3 billion in additional sales of branded Zetia and, in return, gave up approximately $129.8 million in lost authorized generic sales during the first six months after generic entry. The calculation of the $129.8 billion authorized generic sales is explained below.

**(4) The value of the no-AG promise to Glenmark/Par.**

170. Valuing the no-AG agreement to Glenmark/Par is a matter of estimating the additional sales and profits Glenmark/Par made during its six-month generic exclusivity period in 2016, without competition from an authorized generic, as compared to the sales it would have made in the first six months of generic competition starting in December 2011 when, without the benefit of the no-AG agreement, it would have faced competition from Merck's authorized generic.

171. Under competitive conditions, the calculation of Glenmark's sales during the first six months of generic competition starting in December 2011 is identical to the calculation for Merck's authorized generic during this period, because the same assumptions apply to Glenmark's generic as to Merck's. Actual sales of branded Zetia in the U.S. were approximately $1.298 billion in 2011. Assuming that Glenmark/Par's generic and Merck's authorized generic captured 80% of Zetia's sales, split those sales equally, and sold the generic at a price equal to 50% of the brand price, each company would have generated sales of $129.8 million during the six-month exclusivity period ($1.298 billion x .8 x .5 x .5 x .5). Thus, the value of generic sales by Glenmark in 2011, facing competition from Merck's authorized generic, would have been approximately $129.8 million.

172. Under the no-AG agreement, however, Glenmark/Par would now obtain (a) all (rather than 50%) of generic Zetia sales in the first six months of generic launch (because there was no authorized generic sharing the market); (b) a higher generic price equal to approximately 80% of the branded price rather than 50% of the branded price (because there was no authorized generic driving down price); and (c) the advantage of competing in a market that would grow in size over the five-year delay period. From 2011 to 2016, annual sales of branded Zetia actually more than doubled, from $1.298 billion to $2.6 billion.

173. Without competition from Merck's authorized generic, Glenmark/Par could expect to capture 80% of the sales of the branded product in 2016 and could price its generic product at about 80% of the brand's price. Glenmark/Par also could expect the market to grow significantly from 2011 to 2016. Using the conservative assumption that the market was expected to grow by 50% during that time period, from approximately $1.298 billion to approximately $1.947 billion, Glenmark/Par could expect to achieve sales of approximately $623 million during its exclusivity period beginning in December 2016 ($1.947 x .5 x .8 x .8).

174. Thus, the agreement with Merck to delay Glenmark/Par's launch of generic Zetia until December 2016 was worth nearly $500 million in additional sales to Glenmark/Par ($623 million - $129.8 million = $493.2 million). Glenmark/Par would be expected to keep at least 80% of these additional sales dollars as profit.

**N. 2010-2013: Merck seeks another reissue and sues more generics.**

**(1) Summer 2010: Merck admits invalidity and seeks reissue of the RE'721 patent.**

175. On June 9, 2010, within a month after its settlement with Glenmark, Merck applied to the PTO for reissuance of the RE'721 patent. Again, to obtain reissue, the applicant must identify an error and attest, under oath, that the original patent is wholly or partly inoperative or invalid. Merck and its agents admitted that the RE'721 patent was invalid, citing inherent anticipation as the reason (as Glenmark had argued).

176. In the required declaration accompanying its reissue application, Mark Russell, legal director of patents for Schering Corporation attested to an error, and conceded that Glenmark's inherent anticipation argument was correct:

- "I have reviewed and understand the content of the above identified specification, including the claims . . . ."

- "I verily believe the original patent to be wholly or partly inoperative or invalid, for the reasons described below . . . by reason of the patentee claiming more than he had the right to claim in the patent."

- "At least one error upon which reissue is based is described as follows: At least one claim of RE37,721 E is potentially inherently anticipated by International published patent application WO 93/02048, filed July 21, 1992 (PCT/US92/05972) and published February 4, 1993 ("the '048 PCT publication"). See also European patent application EP 0524595 A1. In infringement litigation involving RE37,721 E, defendants have alleged that the PCT'048 publication recites, in Example 9, a compound, that when administered to mammals, as also reported in the PCT'048 publication, metabolizes into one or more compounds that fall within the scope of at least claims 1 of RE37,721 E."

- "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this declaration is directed."

177. In Merck's preliminary remarks, attorneys Carl A. Morales and James F. Haley, Jr. of Ropes and Gray LLP, attorneys/agents for reissue applicants, made similar statements about inherent anticipation and invalidity being the basis for seeking reissue, and proposed amendments to the claims that ostensibly addressed these problems, namely cancelling claims 1-2 and 4-6 and amending claims 3 and 7-9.

**(2) Summer 2010: Merck sues Mylan and Teva for infringing the RE'721 patent; both counterclaim.**

**(a) The *Mylan* litigation.**

178. In or about April 2010, Mylan Pharmaceuticals, Inc. filed a paragraph IV ANDA for generic Zetia.

179. Mylan sent its paragraph IV notice for Zetia to Merck on May 25, 2010.

180. On June 16, 2010, a week after it filed its latest reissue application, Merck sued Mylan for infringement of the RE'721.[19]

181. Mylan counterclaimed, seeking declarations that both patents were invalid and unenforceable, also asserting claims for damages under the federal antitrust laws and state unjust enrichment laws. Mylan raised many of the arguments initially raised by Glenmark.

**(b) The *Teva* litigation.**

182. On July 21, 2010, Teva Pharmaceuticals notified Merck that Teva had filed ANDA 78-724 for approval to make generic Zetia, including a paragraph IV certification that the listed patents were invalid and unenforceable.

183. On September 1, 2010, Merck filed suit against Teva for infringement of the '966 and RE'721 patents in the District of New Jersey. Later that month, Merck formally agreed not to assert the '106 and '058 patents against Teva.

**O. Spring 2011: The Federal Circuit functionally overturns the *Glenmark* "error" summary judgment decision.**

184. In April 2011, shortly before the '115 patent was reissued for a second time, the Court of Appeals for the Federal Circuit reversed the Board of Patent Appeals and Interferences' ruling in *Ex parte Tanaka*. In *Tanaka*, the Federal Circuit recognized "the narrow rule" permitting applicants to add "dependent claims as a hedge against possible invalidity," noting that this rule "has been embraced as a reasonable interpretation of the reissue statute by this court and its predecessor for nearly fifty years."

[19] Merck initially asserted that Mylan's Zetia product infringed the '966 patent but withdrew that allegation part way through the litigation. Mylan had earlier filed an ANDA for Vytorin, a Merck product also marketed to combat high cholesterol that includes ezetimibe as one of two active ingredients. Merck's patent infringement suit against Mylan claiming infringement of the RE'721 and '966 patents by the Vytorin ANDA had been filed in December of 2009 and was pending before Judge Linares in the District of New Jersey at the time of the Merck-Glenmark settlement. The Vytorin and Zetia cases against Mylan were consolidated for all purposes in September 2010.

185. While this decision effectively overturned the rationale behind the earlier *Glenmark* summary judgment about the technical requirements for invoking the reissue statute, it did not in any way undermine any of Glenmark's other arguments regarding invalidity or unenforceability of the RE'721.

**(3) Summer 2011: Merck obtains reissuance of RE'721 patent (RE'461).**

186. On June 14, 2011, the RE'721 patent was reissued as U.S. Patent No. RE42,461.

187. The RE'461 patent as reissued (or as re-reissued in this case) included only claims 8 through 13, and parts of claims 3 and 7, of the RE'721 patent.

**(4) Summer 2011-2012: The Mylan and Teva litigations resolve.**

**(a) 2011: Schering and Teva settle.**

188. On July 7, 2011, before any substantive rulings in the case and while its parallel case against Mylan was pending, Merck settled with Teva. Judge Linares entered a consent judgment that prohibited Teva from launching generic Zetia before April 25, 2017. No other terms of the settlement were made public.

**(b) 2011: The Court denies Merck's motion for summary judgment of inequitable conduct.**

189. On July 25, 2011, Merck filed an amended complaint against Mylan, substituting the newly reissued RE'461 patent for the RE'721 patent.

190. On August 19, 2011, Mylan filed an answer, affirmative defenses, and counterclaims to Merck's amended complaint. In addition to invalidity based on inherent anticipation and unenforceability based on failure to disclose prior art, Mylan also alleged that the patents were unenforceable because of an intentional failure to disclose one of the inventors of ezetimibe.

191. On August 22, 2011, the court denied Merck's motion for judgment on Mylan's defense of inequitable conduct for failure to disclose prior art to the PTO, holding that "Mylan

has put forth sufficient indirect and circumstantial evidence from which a reasonable fact finder could conclude that Schering had knowledge of the materiality of the withheld prior art," and that "a deliberate decision to withhold that information could . . . be reasonably inferred from the evidence already presented."[20]

192. On the same day, Judge Linares granted in part Merck's motion for summary judgment against Mylan, ruling that Mylan's ANDA did infringe claims 3, 10, 11, and 12.

193. On September 30, 2011, Merck indicated that it would no longer be asserting any claims of the '966 patent against Mylan.

194. On November 18, 2011, Mylan sent a letter to the Court confirming that it would be withdrawing a defense, namely its claim "based on the non-disclosure of information demonstrating a relationship between compounds claimed in predecessor patents and metabolites of a prior art compound." This withdrawal "thereby reduc[ed] the issues to be tried before the Court on December 5, 2011." Mylan explained that this was done "in the interest of further streamlining the issues remaining for trial" and "having considered the time allotted by the Court for presentation of issues by the parties." Mylan also specifically clarified that it had "not withdrawn its additional defenses based on inequitable conduct, including those related to improper inventorship."

195. Mylan's choice to pursue the inventorship issue rather than other arguments raised earlier in the litigation does not reflect the relative substantive merits of those arguments/ defenses, or Mylan's own evaluation of them. Instead, the choice simply reflected the untenable position in which Mylan found itself: Mylan had a limited amount of time to present its case, so Mylan picked a single, discrete issue to try.

[20] The court also noted that "Schering does not appear to dispute that it had knowledge of the metabolite information during prosecution."

196. Mylan knew when it was deciding on its litigation strategy in fall 2011 that even if it won the patent litigation, it would enjoy no regulatory or even *de facto* exclusivity. It knew that Zetia was a blockbuster drug, and that many other generic manufacturers had filed or would ultimately file ANDAs seeking to market generic Zetia. Mylan further knew that both of the previously announced Glenmark and Teva agreements may have included so-called "acceleration clauses" that would permit Glenmark and Teva to enter the market as soon as any other generic manufacturer – such as Mylan – entered. And it knew that, in order to trigger Glenmark's 180-day exclusivity, it would have to prevail in the patent case all the way through the Federal Circuit. Thus, regardless of the time and resources that Mylan poured into trying to win the patent litigation, the most it could hope to win would be (at best) a one-third or one-fourth share or (at worst) a one-seventh share of sales made at a price driven to down near marginal cost. Mylan's litigation strategy reflected the choice of not necessarily the best substantive defense, but the cheapest and fastest within the practical constraints.[21]

**(5) 2012: After a trial, the Mylan court found no inequitable conduct on inventorship (only).**

197. Judge Linares held a bench trial in December 2011, solely on the issue of the claimed unenforceability of the RE'461 patent due to Merck's alleged inequitable conduct based on Merck's alleged misrepresentation of the inventorship of the RE'461 patent. The trial did not address any allegations that the RE'461 patent was invalid as obvious over prior art, or any allegations of inequitable conduct based on Merck's failure to disclose invalidating prior art.

[21] Mylan was the first-filer with respect to another drug (Vytorin) involving the same patents at dispute in its Zetia litigation against Merck. But Mylan knew by Fall 2011 that: (1) it would not be entitled to 180-day exclusivity with respect to Vytorin because it would fail to get timely FDA tentative approval; and (2) other generic manufacturers would enter the market with generic Vytorin before or at the time that Mylan entered, even if it won the Vytorin patent case.

198. On April 27, 2012, the court ruled that Mylan had failed to prove inequitable conduct on the inventorship issue and therefore that the RE'461 patent was not invalid or unenforceable on that basis.[22]

199. Later, on August 7, 2013, Mylan's ANDA for Zetia received tentative approval from the FDA. To date, Mylan has not launched a generic version of Zetia in the U.S.

**(6) 2012-2013: Schering sues Sandoz; Sandoz counterclaims; the parties settle.**

200. In August 2012, Sandoz notified Merck that Sandoz had filed ANDA 203-931 for approval to market generic Zetia.

201. On September 27, 2012, Merck sued Sandoz for infringement of the RE'461 patent in the District of New Jersey. In its amended complaint filed May 29, 2013, Merck alleged that the purpose of Sandoz's ANDA submission was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's generic Zetia prior to the expiration of the RE'461, '966, '106, and '058 patents. In its answer to the amended complaint filed July 26, 2013, Sandoz admitted that it had sought approval to manufacture and sell generic Zetia prior to the expiration of those patents, and further admitted that Sandoz intended to manufacture and sell generic Zetia "immediately and imminently upon approval of ANDA No. 203931 in light of potential third party exclusivity rights." Sandoz pleaded affirmative defenses including the unenforceability and invalidity of the RE'461 patent.

202. Sandoz also counterclaimed for a declaratory judgment of the unenforceability of the RE'721 and RE'461 patents, the invalidity and Sandoz's non-infringement of one or more of the claims of those two patents as well as the '106 and '058 patents. Sandoz alleged, inter alia, that all the claims of the RE'721 and RE'461 patents were unenforceable due to inequitable

[22] Mylan appealed the verdict, but on February 7, 2013, the Federal Circuit Court of Appeals affirmed.

conduct because Merck had "failed to disclose publications concerning metabolites of a prior art compound (compound SCH 48461)." Specifically, Sandoz alleged that the publications Merck withheld during prosecution of the RE'721 and RE'461 patents described "metabolic studies of SCH 48461 from which the examiner could determine the structure of metabolites of SCH48461, and that relevant metabolites were inherently formed by the preparation and administration of SCH 48461, as disclosed in [the PCT'048] patent." Sandoz also alleged that the Van Heek 1997 article had claimed the discovery of ezetimibe in conjunction with Dr. Rosenblum in 1995 and described the "large chemical synthesis program [that] evolved to discover a more potent backup compound for SCH 48461," including the addition of "[a] benzylic hydroxyl group … to SCH 53695 and several sites that were readily metabolized in SCH 48461 were blocked with fluorines resulting in [ezetimibe]." Sandoz additionally averred that the Dugar 1996 article, the Rosenblum I 1995 abstract, and the other prior art publications discussed above had specifically disclosed that two disclosed compounds, dubbed compound 57a and compound 58, were metabolites of SCH 48461 and thus inherently disclosed by the teachings of the prior art PCT'048 patent.

203. On September 3, 2013, the court ordered Sandoz to provide its ANDA to Merck by September 6, 2016 (ECF 46) and ordered Merck to file its response to Sandoz's counterclaims on or before September 17, 2013.

204. On September 5, 2013, before the pleadings in the case were closed, and before any further proceedings or any substantive rulings in the case, Merck and Sandoz settled all issues in the patent infringement litigation. Judge Linares entered a consent judgment prohibiting Sandoz from launching generic Zetia before April 25, 2017. No other terms of the settlement were made public.

**P. 2016: Glenmark/Par launches a generic form of Zetia; Merck does not.**

205. Glenmark's ANDA 78-560 received final FDA approval on June 26, 2015. In its final approval letter, the FDA reconfirmed that Glenmark was entitled to 180 days of market exclusivity upon launch.

206. On December 12, 2016, Glenmark/Par launched its generic Zetia, which its press release of that date described as "the first and only generic version" of Zetia in the United States.

207. From December 12, 2016, through June 10, 2017, Glenmark/Par's product was the only generic version of Zetia sold in the U.S. market.

208. Merck refrained from launching an authorized generic version of Zetia during Glenmark's 180-day exclusivity period pursuant to the no-AG commitment in the parties' unlawful settlement agreement. Merck concluded that launching an AG on June 10, 2017 was not economically viable, but that launching an AG three weeks earlier would have been economically viable. Given Merck's recognition that launching an AG only three weeks before the expiration of Glenmark/Par's 180-day exclusivity would have been profitable, there is no doubt that Merck would have launched an AG simultaneously with the launch of Glenmark/Par's generic if Merck had not agreed to refrain from doing so.

**Q. 2017: 180 days later, five more generics launch.**

209. On or about June 10, 2017 – the day Glenmark/Par's exclusivity expired – the FDA approved ANDAs for generic Zetia previously filed by seven competitor companies: Teva (ANDA 78-724), Sandoz (ANDA 203-931), Amneal (ANDA 208803), Apotex (ANDA 208332), Ohm Laboratories (ANDA 207311), Zydus (ANDA 204331), and Watson Laboratories (ANDA 200831).

210. Five of these manufacturers—Teva, Sandoz, Amneal, Apotex and Ohm Laboratories—launched a generic Zetia product in June 2017, shortly after receiving FDA

approval. Zydus launched its generic Zetia product in August 2017. The seventh manufacturer, Watson Laboratories, had sold its generic drug business to Teva before June 2017 and so did not launch a generic Zetia product.

211. An eighth ANDA, filed by Aurobindo (ANDA 209838), was approved in August 2017 and Aurobindo launched the same month. An additional ANDA, filed by Alkem Laboratories (ANDA 209234), was approved in December 2017, and launched the same month.

212. Whereas only brand-name Zetia tablets were available to purchasers and consumers before December 2016, and only brand-name Zetia and Glenmark/Par's generic tablets were available from December 2016 to June 2017, by July of 2017 there were six generics available on the market in addition to branded Zetia, and by September of 2017 there were eight generics in addition to branded tablets.

213. The average retail price of ezetimibe tablets dropped from $10 per pill before Glenmark/Par's launch to less than $1 per pill as of December 1, 2017.

214. Absent the no-AG promise, Merck would have launched an authorized generic during Glenmark/Par's 180-day exclusivity period, taking approximately 50% of Glenmark's generic sales and substantially lowering the price that drug purchasers paid for generic Zetia. Absent the no-AG promise, Glenmark/Par would not have agreed to delay its launch until December 12, 2016, and instead would have entered the market much sooner than it did. Additional generics would have entered the market six months later and further driven down prices.

215. The settlement with Glenmark/Par enabled Merck to continue to receive monopoly profits until December 12, 2016, and enabled Glenmark/Par to earn supracompetitive profits for 180 days thereafter, with Glenmark/Par thereby effectively sharing in the monopoly profits that the agreement made possible. The reverse payment agreement not only delayed

Glenmark/Par's own entry into the market, but also created a bottleneck that blocked all other would-be generic Zetia competitors by postponing the start (and thus also the conclusion) of Glenmark/Par's 180-day first-filer exclusivity period. Absent Glenmark/Par's unlawful agreement to delay its entry until December 12, 2016, these or other generic manufacturers would have filed their ANDA applications earlier and would have been ready, willing, and able to enter the market as soon as Glenmark/Par's 180-day exclusivity expired.

**R. The no-AG promise was a large reverse payment.**

216. The no-AG payment to Glenmark/Par was large, estimated (as explained above) to be worth nearly $500 million in sales. It far exceeded any estimate of the litigation expenses Merck saved by settling the patent case with Glenmark.[23]

217. Merck's reverse payment to Glenmark/Par guaranteed two distinct periods of suppressed competition: (a) the period before generic competition, during which Merck and Glenmark/Par allocated 100% of sales in the relevant market to Merck; and (b) the 180-day exclusivity period after Glenmark/Par's entry, during which Merck and Glenmark/Par allocated 100% of generic sales to Glenmark/Par. So, purchasers were overcharged during both periods: before Glenmark/Par's entry, they were forced to pay overcharges for branded Zetia; and during Glenmark/Par's exclusivity period, they were forced to pay overcharges for generic Zetia. Moreover, the unlawful agreement had the additional anticompetitive effect of delaying the entry of all of the other generic competitors.

218. Defendants have no procompetitive explanation or justification for the reverse payment agreement.

[23] One 2015 survey of the cost of patent litigation found that litigation expenses for a case such as the one between Merck and Glenmark/Par range from $3.7 million to $6.3 million. *AIPLA 2015 Report of the Economic Survey,* IPICS, http://www.patentinsuranceonline.com/wpcontent/uploads/2016/02/AIPLA-2015-Report-of-the-Economic-Survey.pdf (last visited Jan. 11, 2018).

219. But for the reverse payment settlement agreement between Merck and Glenmark/Par, Glenmark could and would have entered the market much sooner than it did, as early as December 6, 2011, with immediate competition from a Merck authorized generic and full competition with other generics by approximately May 2012. Instead, Glenmark/Par did not release its generic until December 12, 2016, Merck never launched an authorized generic, and generic entry by other manufacturers could not occur until June 12, 2017.

## VI. INTERSTATE COMMERCE

220. The drugs at issue in this case are sold in interstate commerce. Defendants' unlawful activities, as alleged above, have occurred in, and have had a substantial impact on, interstate commerce.

## VII. MARKET EFFECTS AND CONTINUING INJURY TO GIANT EAGLE

221. Merck's U.S. sales of Zetia were approximately $1.3 billion in 2010, $1.4 billion in 2012, and $2.6 billion in 2016. These amounts are billions of dollars greater than the sales that Merck would have achieved absent Defendants' unlawful scheme to impair generic competition. Generic Zetia products would have been priced at a fraction of the cost of brand Zetia and would have quickly captured the vast majority of the market for ezetimibe.

222. Merck's and Glenmark/Par's unlawful agreement impaired and delayed the sale of generic Zetia in the United States and unlawfully enabled Merck to sell its branded Zetia at monopoly prices, and then allowed Glenmark/Par to sell generic Zetia at supracompetitive, artificially inflated prices for an additional six months. But for Merck's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Zetia, at a much earlier date.

223. But for Defendants' anticompetitive conduct, Giant Eagle would have: (1) purchased lower-priced generic Zetia, instead of the higher-priced brand Zetia, during the period

when Glenmark/Par delayed its entry to the market; and (2) paid a lower price for generic Zetia products beginning in December 2016 because multiple generic Zetia products would have entered the market years earlier.

224. Giant Eagle has incurred substantial loss and damage to its business and property in the form of overcharges.

## VIII. MARKET POWER AND MARKET DEFINITION

225. The agreement between Merck and Glenmark/Par was a *per se* unlawful horizontal market-allocation agreement, as to which allegations and proof of market power are unnecessary. To the extent market power and/or market definition are found to be required, Giant Eagle alleges them below.

226. Before December 12, 2016, Merck had monopoly power in the market for ezetimibe because it had the power to exclude competition and/or raise or maintain the price of ezetimibe at supracompetitive levels without losing enough sales to make supracompetitive prices unprofitable. Merck was able to extend and maintain its monopoly power for an additional five years by means of its unlawful agreement with Glenmark/Par.

227. Branded Zetia does not exhibit significant, positive cross-elasticity of demand with respect to price with any other pharmaceutical product or treatment for hypercholesterolemia other than AB-rated generic versions of Zetia. That is, in the absence of AB-rated generics, a small but significant and non-transitory increase in the price of Zetia would not cause Merck to lose sufficient sales to other drugs to make the price increase unprofitable.

228. Branded Zetia is differentiated from all other ezetimibe products, and all other hypercholesterolemia treatments, other than the AB-rated generic versions of brand Zetia.

229. Merck needed to control only brand Zetia and its AB-rated generic equivalents, and no other products, in order to maintain the price of ezetimibe profitably at supracompetitive

prices. Only the market entry of competing, AB-rated generic versions would prevent Merck from maintaining extremely high and profitable prices for Zetia without losing substantial sales.

230. Defendants had, and exercised, the power to exclude generic competition to branded Zetia.

231. At all material times, high barriers to entry, including regulatory protections and high costs of entry and expansion, protected branded Zetia from the forces of price competition.

232. There is direct evidence sufficient to show Merck's monopoly power without the need to engage in market definition and calculate market shares. That evidence includes, among other things, the large reverse payment made to Glenmark/Par and the extremely high monopoly profits Merck earned on branded Zetia, neither of which would have occurred in a competitive market. To the extent that proof of monopoly power by defining a relevant product market is required, the relevant antitrust product market is the market for Zetia and its AB-rated generic equivalents, and the relevant geographic market is the United States.

233. Merck's market share in the relevant market was 100% until December 12, 2016, after which Merck and Glenmark/Par, collectively, had a 100% market share in the relevant market until June of 2017, when Teva, Mylan, Sandoz, Amneal, Apotex, Ohm Laboratories/Sun Pharmaceuticals and Zydus all launched generic Zetia products.

## IX. CONCEALMENT TOLLED THE STATUTE OF LIMITATIONS

234. Giant Eagle has a cause of action against Defendants for overcharges each time they (or their assignors) purchased Zetia or generic Zetia at a price higher than the price it would have paid but for Defendants' antitrust violations. Accordingly, Giant Eagle is entitled to recover overcharges on all purchases made within four years prior to the filing of the *FWK Holdings* lawsuit, *i.e.*, all purchases on or after January 16, 2014.

235. In addition, Giant Eagle is entitled to recover damages on purchases made prior to January 16, 2014, because Defendants fraudulently concealed their unlawful conduct and Giant Eagle did not and could not have discovered that conduct by the exercise of reasonable diligence, thereby tolling the statute. Merck's payment to Glenmark in the form of a no-AG promise was not discoverable until, at the earliest, after Glenmark launched its generic ezetimibe in December 2016 and Merck did not launch an authorized generic. Merck and Glenmark had previously disclosed only cursory information about the existence of the settlement.

236. Defendants' scheme was self-concealing, and, in addition, Defendants actively concealed their conspiracy to avoid detection.

237. Defendants wrongfully and affirmatively concealed the existence of their ongoing combination and conspiracy from Giant Eagle by, among other things:

a. Concealing the fact of Merck's agreement not to launch a competing authorized generic Zetia product in exchange for Glenmark/Par's agreement not to market its competing generic product until December 12, 2016;

b. Concealing the fact that the purpose of the no-AG agreement was to provide compensation to Glenmark/Par in connection with the settlement of the patent litigation and the December 2016 entry date for Glenmark/Par's generic product; and

c. Filing documents with the United States Securities and Exchange Commission that failed to disclose the existence or nature of the payments made.

238. Because the scheme and conspiracy were both self-concealing and affirmatively concealed by the defendants, Giant Eagle had no knowledge of the conspiracy and could not have uncovered it before, at the earliest date, December 2016, through the exercise of reasonable diligence.

239. Giant Eagle also lacked the facts and information necessary to form a good faith basis for believing that any legal violations had occurred.

240. As a result of Defendants' fraudulent concealment, the applicable statute of limitations was tolled.

## X. CLAIMS FOR RELIEF

### COUNT ONE: VIOLATION OF 15 U.S.C. § 1 (*PER SE*)

241. Giant Eagle incorporates by reference the allegations in the preceding paragraphs.

242. On or about May 10, 2010, Merck and Glenmark/Par entered into an unlawful horizontal market-allocation agreement. Such agreements are unlawful *per se*—*i.e.*, they are conclusively presumed to have substantially adverse effects on competition in the relevant market. Proof of actual adverse effects or of market power, whether direct or indirect, is unnecessary in a *per se* case.

243. The agreement between Merck and Glenmark/Par was a *per se* unlawful horizontal market-allocation agreement which allocated all sales of Zetia and its AB-rated equivalents to Merck during the period from December 2011 through December 2016 and which allocated all sales of AB-rated generic Zetia to Glenmark from December 2016 through June 2017. Glenmark/Par agreed not to compete with Merck from December 2011 through December 2016, and Merck agreed not to compete with Glenmark/Par from December 2016 through June 2017. Horizontal market-allocation agreements, including temporal horizontal market-allocation agreements, are illegal *per se*.

244. But for Defendants' antitrust violation, generic competition to Zetia would have begun as early as December 2011. Giant Eagle and its assignors would have paid lower prices for ezetimibe from December 2011 until today and into the future.

245. As a result of Defendants' antitrust violation, Giant Eagle has been injured in its business or property. Giant Eagle's injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

**COUNT TWO: VIOLATION OF 15 U.S.C. § 1 (RULE OF REASON)**

246. Giant Eagle incorporates by reference the allegations in the preceding paragraphs.

247. On or about May 10, 2010, Merck and Glenmark/Par entered into a reverse-payment agreement pursuant to which Merck made a large and unjustified payment to Glenmark/Par to avoid the risk of generic competition and maintain Merck's monopoly power in the relevant market. That agreement had substantially adverse effects on competition in the relevant market and is unlawful under the rule of reason.

248. From the launch of branded Zetia in 2002 through December 12, 2016, Merck possessed monopoly power in the relevant market. Its unlawful agreement with Glenmark/Par allowed it to maintain that monopoly power. But for the unlawful agreement, Merck would have seen its monopoly dissipate in the face of generic competition as early as December 6, 2011, and in any event well before December 12, 2016.

249. Rather than competing on the merits, Merck and Glenmark/Par entered into a reverse-payment agreement under which Merck paid Glenmark millions of dollars to delay the launch of generic Zetia for five years. The purpose and effect of the agreement were to: (a) delay the launch of generic Zetia and thereby maintain Merck's monopoly power; (b) compensate Glenmark/Par for the delay by allowing it to sell generic Zetia for six months without competition from an authorized generic, thereby allowing Glenmark/Par to earn supracompetitive prices as the monopoly generic; and (c) raise and maintain the prices paid by Giant Eagle and other purchasers for both branded and generic Zetia.

250. There is and was no legitimate, non-pretextual, procompetitive business justification for the unlawful agreement that outweighs its anticompetitive effects.

251. As a result of Defendants' antitrust violation, Giant Eagle has been injured in its business or property. Giant Eagle's injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

**COUNT THREE: VIOLATION OF 15 U.S.C. § 2**

252. Giant Eagle incorporates by reference the allegations in paragraphs 1 through 246 above.

253. Merck and Glenmark/Par conspired to monopolize the relevant market and committed overt acts in furtherance of their unlawful conspiracy.

254. Merck and Glenmark/Par each had a specific intent to achieve or maintain monopoly power in the relevant market. By paying Glenmark/Par hundreds of millions of dollars to delay the launch of its generic product, Merck manifested a specific intent to maintain its monopoly from at least 2011 to 2016. By accepting Merck's payment, Glenmark/Par manifested its specific intent to allow Merck to maintain its monopoly from at least 2011 to 2016, and its specific intent to obtain market power as the sole source of generic Zetia from December 2016 to June 2017.

255. As a result of Defendants' antitrust violation, Giant Eagle has been injured in its business or property. Giant Eagle's injury is injury of the type the antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

## XI. DEMAND FOR JUDGMENT

256. WHEREFORE, Giant Eagle prays for judgment against Defendants and for the following relief:

A. A declaration that the conduct alleged herein is in violation of Sections 1 and 2 of the Sherman Act;

B. An award of Giant Eagle's overcharge damages, in an amount to be determined at trial, trebled;

C. An award of Giant Eagle's costs of suit, including reasonable attorneys' fees as provided by law; and

D. Such other and further relief as the Court deems just and proper.

## XII. JURY DEMAND

Giant Eagle demands a trial by jury of all issues so triable.

Date: June 30, 2022

Respectfully submitted,

*/s/ John F. Sawyer*

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